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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1601

RIN 3046–AB26

2024 Adjustment of the Penalty for Violation of Notice Posting Requirements

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, this final rule adjusts for inflation the civil monetary penalty for violation of the notice-posting requirements in Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Genetic Information Non-Discrimination Act, and the Pregnant Workers Fairness Act.

DATES: This final rule is effective February 16, 2024.

FOR FURTHER INFORMATION CONTACT: Kathleen Oram, Assistant Legal Counsel, (202) 921–2665 or kathleen.oram@eeoc.gov, Office of Legal Counsel, Equal Employment Opportunity Commission, 131 M St. NE, Washington, DC 20507. Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 921–3191 (voice) or 1–800–669–6820 (TTY), or 1–844–234–5122 (ASL video phone).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 711 of the Civil Rights Act of 1964 (Title VII), which is adopted by reference in section 105 of the Americans with Disabilities Act (ADA), section 207(a)(1) of the Genetic Information Non-Discrimination Act (GINA), and section 104(a)(1) of the Pregnant Workers Fairness Act (PWFA), and implemented by the Equal Employment Opportunity Commission

(EEOC) in 29 CFR 1601.30(a), every employer, employment agency, labor organization, and joint labor-management committee controlling an apprenticeship or other training program covered by Title VII, ADA, GINA, or PWFA, must post notices describing the pertinent provisions of these laws. Covered entities must post such notices in prominent and accessible places where they customarily maintain notices to employees, applicants, and members. 29 CFR 1601.30(a). Failure to comply with this posting requirement is subject to a monetary penalty. 29 CFR 1601.30(b).

Section 5(b) of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act),¹ which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, requires the EEOC to annually adjust the amount of the penalty for non-compliance. Under the 2015 Act, the EEOC has no discretion over whether or how to calculate this inflationary adjustment. In accordance with section 6 of the 2015 Act, the EEOC will apply the adjusted penalty only to those assessed after the effective date of the adjustment.

II. Calculation

The adjustment set forth in this final rule follows guidance under the 2015 Act from the Office of Management and Budget (OMB)² and is calculated by comparing the Consumer Price Index for all Urban Consumers (CPI-U) for October 2022 with the CPI-U for October 2023, resulting in an inflation adjustment factor of 1.03241. The inflation adjustment factor (1.03241) was multiplied by the most recent civil penalty amount (\$659) to calculate the inflation-adjusted penalty level (\$680.35819), which is then rounded to the nearest dollar (\$680). Accordingly, the Commission is now adjusting the maximum penalty per violation specified in 29 CFR 1601.30(b) from \$659 to \$680.

¹ Public Law 114–74, Sec. 701(b), 129 Stat. 599.

² Memorandum from Shalanda D. Young, Director, Office of Management and Budget, to Heads of Executive Departments and Agencies, M–24–07, Dec. 19, 2023, M–24–07 at 1 (“[b]ased on the Consumer Price Index (CPI-U) for the month of October 2023, not seasonally adjusted, the cost-of-living adjustment multiplier for 2024 is 1.03241”).

III. Regulatory Procedures

Administrative Procedure Act

The Administrative Procedure Act (APA) provides an exception to the notice and comment procedures where an agency finds good cause for dispensing with such procedures, on the basis that they are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(3)(B). The Commission finds that this rule meets the exception because the 2015 Act requires an inflationary adjustment to the civil monetary penalty, it prescribes the formula for calculating the adjustment to the penalty, and it provides the Commission with no discretion in determining the amount of the published adjustment. Accordingly, the Commission is issuing this revised regulation as a final rule without notice and comment.

Executive Order 12866

This rule is not a significant regulatory action as that term is defined in Executive Order 12866. The inflationary adjustment’s cumulative impact on the violations found each year falls well below the \$200 million threshold for significant regulatory action under E.O. 12866, as revised by E.O. 14094, and it otherwise fails to meet the definition of a significant regulatory action.

Paperwork Reduction Act

This final rule contains no new information collection requirements, and therefore, will create no new paperwork burdens or modifications to existing burdens that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) only requires a regulatory flexibility analysis when the APA requires notice and comment procedures, or the agency otherwise issues such a notice. As stated above, notice and comment is neither required nor being used for this rule. Accordingly, the Regulatory Flexibility Act does not apply.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the

private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501–1571).

Congressional Review Act

This regulation is a rule subject to the Congressional Review Act (CRA) (5 U.S.C. 801–808), but is not a “major” rule that cannot take effect until 60 days after it is published in the **Federal Register**. Therefore, the EEOC will submit this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the effective date of the rule.

List of Subjects in 29 CFR Part 1601

Administrative practice and procedure.

For the Commission.

Charlotte A. Burrows,
Chair, Equal Employment Opportunity Commission.

Accordingly, the Equal Employment Opportunity Commission amends 29 CFR part 1601 as follows:

PART 1601—PROCEDURAL REGULATIONS

- 1. The authority citation for part 1601 continues to read as follows:

Authority: 42 U.S.C. 2000e to 2000e–17; 42 U.S.C. 12111 to 12117; 42 U.S.C. 2000ff to 2000ff–11; 28 U.S.C. 2461 note, as amended; Pub. L. 104–134, Sec. 31001(s)(1), 110 Stat. 1373.

- 2. Section 1601.30 is amended by revising paragraph (b) to read as follows:

§ 1601.30 Notices to be posted.

* * * * *

(b) Section 711(b) of Title VII and the Federal Civil Penalties Inflation Adjustment Act, as amended, make failure to comply with this section punishable by a fine of not more than \$680 for each separate offense.

[FR Doc. 2024–03177 Filed 2–15–24; 8:45 am]

BILLING CODE 6570–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Parts 1601 and 1626

RIN 3046–AB32

Congressional Disapproval of Update of Commission’s Conciliation Procedures

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule; Congressional Review Act revocation.

SUMMARY: Pursuant to their authority under the Congressional Review Act (CRA), Congress passed, and the President signed, a joint resolution disapproving the Equal Employment Opportunity Commission’s (EEOC or Commission) final rule titled “Update of Commission’s Conciliation Procedures.” Under the joint resolution and by operation of the CRA, this rule has no legal force or effect. The Commission hereby is removing it from the Code of Federal Regulations.

DATES: This final rule is effective February 16, 2024.

FOR FURTHER INFORMATION CONTACT:

Kathleen Oram, Assistant Legal Counsel, Office of Legal Counsel, at kathleen.oram@eeoc.gov or (202) 921–2665 (voice). Requests for this document in an alternative format should be made to the EEOC’s Office of Communications and Legislative Affairs at (202) 921–3191 (voice), 1–800–669–6820 (TTY), or 1–844–234–5122 (ASL video phone).

SUPPLEMENTARY INFORMATION: On October 9, 2020, the Commission published a notice of proposed rulemaking (NPRM) in the **Federal Register**, proposing amendments to its procedural rules governing the conciliation process (85 FR 64079). The Commission published the final rule, titled “Update of Commission’s Conciliation Procedures,” in the **Federal Register** on January 14, 2021 (86 FR 2974) (“Final Rule”). The Final Rule outlined the information that the Commission must provide when undertaking conciliation efforts for charges alleging violations of Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990 (ADA), the Genetic Information Nondiscrimination Act of 2008 (GINA), and the Age Discrimination in Employment Act of 1967 (ADEA). The Final Rule became effective on February 16, 2021.

On May 19, 2021, the United States Senate passed a joint resolution (S.J. Res. 13) disapproving the Final Rule under the Congressional Review Act

(CRA) (5 U.S.C. 801 *et seq.*). The United States House of Representatives passed S.J. Res. 13 on June 24, 2021. The President signed the joint resolution into law as Public Law 117–22 on June 30, 2021. Under Public Law 117–22 and by operation of the CRA, the Final Rule has no force or effect. Accordingly, the Commission is hereby removing the Final Rule from the Code of Federal Regulations (CFR).

This action is not an exercise of the Commission’s rulemaking authority under the Administrative Procedure Act (APA) because the Commission is not “formulating, amending, or repealing a rule” under 5 U.S.C. 551(5). Rather, the Commission is effectuating a change to the Code of Federal Regulations to reflect what congressional and presidential action already has accomplished. Accordingly, the Commission is not soliciting comments on this action, nor is it delaying the effective date.

List of Subjects in 29 CFR Parts 1601 and 1626

Administrative practice and procedure, Equal employment opportunity.

For the reasons set forth above, and pursuant to the CRA (5 U.S.C. 801 *et seq.*) and Public Law 117–22, the Equal Employment Opportunity Commission amends 29 CFR parts 1601 and 1626 as follows:

PART 1601—PROCEDURAL REGULATION

- 1. The authority citation for 29 CFR part 1601 continues to read as follows:

Authority: 42 U.S.C. 2000e to 2000e–17; 42 U.S.C. 12111 to 12117; 42 U.S.C. 2000ff to 2000ff–11; 28 U.S.C. 2461 note, as amended; Pub. L. 104–134, Sec. 31001(s)(1), 110 Stat. 1373.

§ 1601.24 [Amended]

- 2. Amend § 1601.24 by removing paragraphs (d), (e), and (f).

PART 1626—PROCEDURES—AGE DISCRIMINATION IN EMPLOYMENT ACT

- 3. The authority citation for 29 CFR part 1626 continues to read as follows:

Authority: Sec. 9, 81 Stat. 605, 29 U.S.C. 628; sec. 2, Reorg. Plan No. 1 of 1978, 3 CFR, 1978 Comp., p. 321.

- 4. Revise § 1626.12 to read as follows:

§ 1626.12 Conciliation efforts pursuant to section 7(d) of the Act.

Upon receipt of a charge, the Commission shall promptly attempt to eliminate any alleged unlawful practice

by informal methods of conciliation, conference and persuasion. Upon failure of such conciliation the Commission will notify the charging party. Such notification enables the charging party or any person aggrieved by the subject matter of the charge to commence action to enforce their rights without waiting for the lapse of 60 days. Notification under this section is not a Notice of Dismissal or Termination under § 1626.17.

■ 5. Amend § 1626.15 by revising paragraph (d) to read as follows:

§ 1626.15 Commission enforcement.

* * * * *

(d) Upon the failure of informal conciliation, conference and persuasion under section 7(b) of the Act, the Commission may initiate and conduct litigation.

* * * * *

Charlotte A. Burrows,

Chair, Equal Employment Opportunity Commission.

[FR Doc. 2024–03176 Filed 2–15–24; 8:45 am]

BILLING CODE 6570–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 510

North Korea Sanctions 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 North Korea Sanctions Regulations to modify a general license that authorizes certain transactions in support of specified humanitarian activities of nongovernmental organizations. Additionally, OFAC is adding general licenses to authorize the following: transactions related to the exportation and reexportation of items authorized by the U.S. Department of Commerce; the provision of certain agricultural commodities, medicine, and medical devices; and certain journalistic activities in North Korea.

DATES: This rule is effective February 16, 2024.

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

SUPPLEMENTARY INFORMATION:

Electronic Availability

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

Background

On November 4, 2010, OFAC issued the North Korea Sanctions Regulations, 31 CFR part 510 (75 FR 67912, November 4, 2010) (the “Regulations”). Since then, OFAC has amended the Regulations several times. OFAC is now amending the general license at § 510.512 of the Regulations, which authorizes certain transactions in support of specified humanitarian activities of nongovernmental organizations (NGOs) in North Korea, to broaden the activities and transactions authorized, including transactions with certain Government of North Korea entities that are necessary for the provision of services authorized by § 510.512, and make other changes. As a condition of the general license, NGOs relying on the authorization must submit a report to the U.S. Department of State no fewer than 30 days before the commencement of their activity indicating that the NGO's activities have been approved by or notified to the Security Council Committee established pursuant to United Nations Security Council resolution 1718 (2006), or that the NGO's activities do not require such an approval or notification. The U.S. Department of State may notify NGOs within the two-week period following submission of the report to inform them that their activities are not authorized by the NGO general license.

Additionally, this rule adds three new general licenses to the Regulations. Section 510.520 authorizes transactions incident to the exportation or reexportation to North Korea of items (commodities, software, or technology) subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR), that have been licensed or otherwise authorized by the U.S. Department of Commerce under the EAR, including on a “No License Required” (NLR) basis due to the availability of an EAR license exception. Section 510.521 authorizes the provision of certain agricultural commodities, medicine, and medical devices (excluding “luxury goods” as described in 15 CFR 746.4(b)(1)) that are not subject to the EAR to North Korea. Section 510.522 authorizes U.S. news reporting organizations and their employees to engage in certain journalistic activities in North Korea, which OFAC authorizes via specific license. Finally, this rule corrects a

typographic error in the authority citation.

Public Participation

Because this amendment of the Regulations involves a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), as amended, 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”). 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 510

Administrative practice and procedure, Agricultural commodities, Aircraft, Banks, Banking, Blocking of assets, CAPTA List, Diplomatic missions, Foreign financial institutions, Foreign trade, Imports, Journalistic activities, Medical devices, Medicine, Nongovernmental organizations, North Korea, Patents, Secondary sanctions, Services, Telecommunications, United Nations, Vessels, Workers' Party of Korea.

For the reasons set forth in the preamble, OFAC amends 31 CFR part 510 as follows:

PART 510—NORTH KOREA SANCTIONS REGULATIONS

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

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c, 9201–9255; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 115–44, 131 Stat. 886 (codified in scattered sections of 22 U.S.C.); E.O. 13466, 73 FR 36787, 3 CFR, 2008 Comp., p. 195; E.O. 13551, 75 FR 53837, 3 CFR, 2010 Comp., p. 242; E.O. 13570, 76 FR 22291, 3 CFR, 2011 Comp., p. 233; E.O. 13687, 80 FR 819, 3 CFR, 2015 Comp., p. 259; E.O. 13722, 81 FR 14943,

3 CFR, 2016 Comp., p. 446; E.O. 13810, 82 FR 44705, 3 CFR, 2017 Comp., p. 379.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 2. Revise § 510.512 to read as follows:

§ 510.512 Certain transactions in support of nongovernmental organizations' activities.

(a) Except as provided in paragraph (d) of this section, and subject to the reporting requirements set forth in paragraph (e) of this section, all transactions, including the payment of reasonable and customary taxes, fees, and import duties to, and purchase or receipt of permits, licenses, or public utility services from, the Government of North Korea that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization (NGO) are authorized, provided that the NGO is not a person whose property and interests in property are blocked pursuant to this part.

Note 1 to paragraph (a). The authorization in paragraph (a) of this section includes the exportation or reexportation of items (commodities, software, or technology) not subject to the Export Administration Regulations (15 CFR parts 730 through 774) (EAR) that are ordinarily incident and necessary to activities described in paragraph (b) of this section, except for items described in paragraph (d)(3) of this section. Pursuant to 15 CFR 746.4(a), a license from the Department of Commerce is required to export or reexport any item subject to the EAR to North Korea, except food and medicine designated as EAR99, unless a license exception applies.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education at or below a secondary school level, including combating illiteracy,

increasing access to education at the primary or secondary school level, and assisting education reform projects, provided that such education excludes the subjects of math, sciences, technology, engineering, and computer programming;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) U.S. depository institutions, U.S.-registered brokers or dealers in securities, and U.S.-registered money transmitters are authorized to process transfers of funds on behalf of U.S. or third-country NGOs, including transfers of funds to or from North Korea, in support of the activities authorized by paragraph (a) of this section.

(d) This section does not authorize the following transactions:

(1) The exportation or reexportation of services to, charitable donations to or for the benefit of, or any other transactions involving the Government of North Korea, the Workers' Party of Korea, or any other person whose property and interests in property are blocked pursuant to § 510.201, except as ordinarily incident and necessary to an activity authorized in paragraph (a) of this section;

(2) Partnerships or partnership agreements with any military, intelligence, or law enforcement entity owned or controlled by the Government of North Korea, except as necessary to export or import items to or from North Korea that are licensed or otherwise authorized pursuant to this part or pursuant to the EAR; or

(3) Exportation or reexportation of any item that would not be designated as EAR99 if it were located in the United States, unless exempt or authorized.

(e) NGOs relying on the authorization in paragraph (a) of this section must submit a report to the U.S. Department of State via email at *DPRK-NGO-GL-Notification-DL@state.gov* no fewer than 30 days before commencement of the authorized activity with the following:

(1) *UN Security Council 1718 Committee ("1718 Committee") report.*

(i) If the NGO has received 1718 Committee approval with respect to its activities to be conducted pursuant to this section, a copy of such approval along with the exemption request submitted to the 1718 Committee; or

(ii) If the NGO has not received 1718 Committee approval with respect to its activities to be conducted pursuant to this section, either:

(A) A copy of any 1718 Committee exemption request or notification that has been or will be submitted to the 1718 Committee with respect to the NGO's activities; or

(B) A detailed explanation of why the NGO's proposed activities do not require such an exemption or notification, including:

(1) Items the NGO plans to transport to North Korea related to activities described in paragraph (b) of this section, including items for personal use by persons regularly employed by the NGO;

(2) Estimated or actual dollar value of the transaction(s), as determined by the value of goods, services, or contracts;

(3) The parties involved, including any persons owned, controlled, or acting on behalf of the Government of North Korea or the Workers Party of Korea, as well as financial institutions that may be involved in processing such transactions;

(4) The type and scope of activities conducted; and

(5) The dates or duration of the activities.

(2) *U.S. Department of State confirmation.* The U.S. Department of State may notify an NGO within the 2-week period following submission of the report described in this paragraph (e) to inform the NGO that it may not rely upon this section.

(f) Specific licenses may be issued on a case-by-case basis to authorize NGOs or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects to directly benefit the civilian population of North Korea.

Note 2 to § 510.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 3. Add § 510.520 to read as follows:

§ 510.520 Transactions ordinarily incident to the exportation or reexportation to North Korea of items licensed or otherwise authorized by the Department of Commerce, and related services.

All transactions ordinarily incident to the exportation or reexportation of items (commodities, software, or technology) to North Korea, including transactions with the Government of North Korea or any other person whose property and interests in property are blocked pursuant to § 510.201, and services provided outside North Korea to install, repair, or replace such items, are authorized, provided that the exportation or reexportation of such items to North Korea is licensed or otherwise authorized by the Department of Commerce.

■ 4. Add § 510.521 to read as follows:

§ 510.521 Exportation or reexportation to North Korea of certain agricultural commodities, medicine, medical devices, and replacement parts and components.

(a) All transactions prohibited by § 510.206 that are related to the exportation or reexportation to North Korea of agricultural commodities, medicine, medical devices, or replacement parts or components for medical devices, in each case that are not subject to the Export Administration Regulations (15 CFR parts 730 through 774) (EAR), are authorized, provided that the agricultural commodities, medicine, medical devices, or replacement parts or components:

- (1) Would be designated as EAR99 if they were located in the United States;
- (2) Are not luxury goods as set forth in 15 CFR 746.4(b)(1), including identified as examples of luxury goods in 17 CFR part 746, supplement no. 1;
- (3) Are approved for exportation or reexportation to North Korea by the Security Council Committee established pursuant to United Nations Security Council resolution 1718 (2006), to the extent such approval is required;
- (4) Are not exported or reexported to any military, intelligence, or law enforcement purchaser or importer; and
- (5) Replacement parts are limited to a one-for-one export or reexport basis (*i.e.*, only one replacement part can be exported or reexported to replace a broken or non-operational part).

Note 1 to paragraph (a). Separate authorization from OFAC is required for export or reexport by a U.S. person to North Korea of items that are not subject to the EAR, other than agricultural commodities, medicine, medical devices, or replacement parts or components for medical devices as described in this paragraph. See § 510.512 for a general license authorizing certain transactions by nongovernmental organizations, including exports and

reexports of certain items that are not subject to the EAR.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* The term *agricultural commodities* means products:

(i) That fall within the term “agricultural commodity” as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers for the purposes of food production; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* The term *medicine* means an item that falls within the definition of the term “drug” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical device.* The term *medical device* means an item that:

(i) Falls within the definition of “device” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(ii) Is not on the List of Medical Devices Requiring Specific Authorization, which is maintained on OFAC’s website (www.treasury.gov/ofac) on the North Korea Sanctions page.

Note 2 to § 510.521. Pursuant to 17 CFR 746.4(a), a license from the Department of Commerce is required to export or reexport any item subject to the EAR to North Korea, except food and medicine designated as EAR99, unless a license exception applies.

■ 5. Add § 510.522 to read as follows:

§ 510.522 Journalistic activities and establishment of news bureaus in North Korea.

(a) Subject to the conditions set forth in paragraph (b) of this section, news reporting organizations that are United States persons, and individuals who are United States persons regularly employed by news reporting organizations either as journalists (including photojournalists) or as supporting broadcast or technical personnel, are authorized to engage in the following transactions in North Korea, provided that such transactions are ordinarily incident and necessary to

their journalistic activities or the establishment or operation of a news bureau in North Korea:

(1) Hiring and compensating support staff in North Korea (*e.g.*, stringers, translators, interpreters, camera operators, technical experts, freelance producers, or drivers), persons to handle logistics, or other office personnel as needed;

(2) Leasing or renting office space;

(3) Purchasing, leasing, or renting North Korean-origin goods and services (*e.g.*, mobile phones and related airtime), selling such goods when no longer needed to persons other than the Government of North Korea or Worker’s Party of Korea, or importing them into the United States;

(4) Renting and using telecommunications facilities in North Korea and paying fees or taxes related to the dissemination of information and transmission of news feeds (*e.g.*, fees for satellite uplink facilities, or live news feeds);

(5) Exporting and reexporting to North Korea, and subsequently reexporting from North Korea, equipment that is not subject to the Export Administration Regulations (15 CFR parts 730 through 774) (EAR), and that is ordinarily incident and necessary to journalistic activities, provided that:

(i) Such equipment would be designated as EAR99 if it were located in the United States;

(ii) The exportation or reexportation is approved by the Security Council Committee established pursuant to United Nations Security Council resolution 1718 (2006), to the extent such approval is required; and

(iii) Such equipment remains under the effective control and in the physical possession of the news reporting organization or journalist exporting such equipment while it is in North Korea and is reexported from North Korea to the United States or a third country when no longer needed for journalistic activities in North Korea; and

(6) Paying for all expenses ordinarily incident and necessary to journalistic activities, including sales or employment taxes to the Government of North Korea.

Note 1 to paragraph (a). This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations. Pursuant to 15 CFR 746.4(a), a license from the Department of Commerce is required to export or reexport any item (commodities, software, or technology) subject to the EAR to North Korea, except food and medicine designated as EAR99, unless a license exception applies.

Note 2 to paragraph (a). See § 510.520 for a general license authorizing transactions ordinarily incident to the exportation or reexportation to North Korea of items that are licensed or otherwise authorized by the Department of Commerce.

(b) For the purposes of this section, the term “news reporting organization” means an entity whose primary purpose is the gathering and dissemination of news to the general public.

Note 3 to § 510.522. As of September 1, 2017, the U.S. Department of State has restricted the use of U.S. passports to travel into, in, or through North Korea. See 22 CFR 51.63. U.S. nationals who wish to travel to or within North Korea for the extremely limited purposes that are set forth in Federal regulations must apply for a passport with a special validation from the Department of State. See *travel.state.gov* for additional details.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–03255 Filed 2–15–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2023–0903]

RIN 1625–AA08

Special Local Regulations; Sector Ohio Valley Annual and Recurring Special Local Regulations

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: The Coast Guard is amending and updating its special local regulations for recurring marine parades, regattas, and other events that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). This rule informs the public of regularly scheduled events that require additional safety measures through the establishing of a special local regulation. Through this rulemaking, the current list of recurring special local regulations is updated with revisions, additional events, and removal of events that no longer take place in Sector Ohio Valley’s AOR. When these special local regulations are enforced, certain restrictions are placed on marine traffic in specified areas.

DATES: This rule is effective on March 18, 2024.

ADDRESSES: To view documents mentioned in this preamble as being

available in the docket, go to <https://www.regulations.gov>, type USCG–2023–0903 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Petty Officer Kostas Papakonstantinou, Sector Ohio Valley, U.S. Coast Guard, U.S. Coast Guard; telephone (502) 779–5348, email SECOHV-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Captain of the Port Sector Ohio Valley (COTP) is establishing, amending, and updating its current list of recurring special local regulations codified under 33 CFR 100.801 in Table no. 1, for the COTP Ohio Valley zone.

On December 13, 2023, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Sector Ohio Valley Annual and Recurring Special Local Regulations Update (86 FR 69602). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to those recurring regulated areas. During the comment period that ended January 12, 2024, no comments were received. A detailed description of the changes is provided in the proposed rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Coast Guard is amending and updating the special local regulations under 33 CFR part 100 to include the most up to date list of recurring special local regulations for events held on or around navigable waters within the Sector Ohio Valley AOR. These events include marine parades, boat races, swim events, and others. The current list under 33 CFR 100.801 requires amending to provide new information on existing special local regulations, include new special local regulations expected to recur annually or biannually, and to remove special local regulations that are no longer required. Issuing individual regulations for each new special local regulation, amendment, or removal of an existing special local regulation creates

unnecessary administrative costs and burdens. This rulemaking reduces administrative overhead and provides the public with notice through publication in the **Federal Register** of the upcoming recurring special local regulations.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published December 13th, 2023. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. This rule amends and updates part 100 of 33 CFR by revising the current table for Sector Ohio Valley, and by adding four new recurring special local regulations, removing two special local regulations, and amending twenty-seven special local regulations as described in the NPRM. Vessels intending to transit the designated waterway through the safety zone will only be allowed to transit the area when the COTP, or designated representative, has deemed it safe to do so or at the completion of the event.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

The Coast Guard expects the economic impact of this rule to be minimal, and therefore a full regulatory evaluation is unnecessary. This rule establishes special local regulations limiting access to certain areas under 33 CFR 100 within Sector Ohio Valley’s AOR. The effect of this rulemaking will not be significant because these special local regulations are limited in scope and duration. Deviation from the special local regulations established through this rulemaking may be requested from the appropriate COTP and requests will be considered on a case-by-case basis.

Broadcast Notices to Mariners and Local Notices to Mariners will inform the community of these special local regulations so that they may plan accordingly for these short restrictions on transit. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted areas.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 00 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulation may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you

wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security

Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of special local regulations related to marine event permits for marine parades, regattas, and other marine events. It is categorically excluded from further review under paragraph L(61) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Memorandum for the Record supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. In § 100.801, revise and republish Table 1 to read as follows:

§ 100.801 Annual Marine Events in the Eighth Coast Guard District.

* * * * *

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS

Date	Event/sponsor	Ohio Valley location	Regulated area
1. 3 days—a weekend in March	Oak Ridge Rowing Association/Cardinal Invitational.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
2. 1 day in March	Oak Ridge Rowing Association/US Rowing U19 ID Camp.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee)
3. 1 day a weekend in March	Vanderbilt Rowing/Vanderbilt Invite	Nashville, TN	Cumberland River, Mile 188.0–192.7 (Tennessee).

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio Valley location	Regulated area
4. 2 days— a weekend in March	Oak Ridge Rowing Association/Atomic City Turn and Burn.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
5. 3 days—One weekend in April	Big 10 Invitational Regatta	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
6. 1 day—One weekend in April	Lindamood Cup	Marietta, OH	Muskingum River, Mile 0.5–1.5 (Ohio).
7. 3 days—a weekend in April	Oak Ridge Rowing Association/SIRA Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
8. 2 days—Third or fourth Friday and Saturday in April.	Thunder Over Louisville	Louisville, KY	Ohio River, Mile 597.0–604.0 (Kentucky).
9. 1 day—During the last week of April or first week of May.	Great Steamboat Race	Louisville, KY	Ohio River, Mile 595.0–605.3 (Kentucky).
10. 3 days—a weekend in April	Oak Ridge Rowing Association/Dogwood Junior Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
11. 3 days in May	Oak Ridge Rowing Association/AAC Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
12. 4 days in May	Oak Ridge Rowing Association/ACRA Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
13. 3 Days in May	US Rowing Southeast Youth Championship Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52 (Tennessee).
14. 3 days—a weekend in May	Vanderbilt Rowing/ACRA Henley	Nashville, TN	Cumberland River, Mile 188.0–194.0 (Tennessee).
15. 3 days— a weekend in May	Oak Ridge Rowing Association/SRAA Championships.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
16. 3 days—A weekend in May or June.	Oak Ridge Rowing Association/Dogwood Masters.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
17. 1 day—a weekend in May	World Triathlon Corporation/IRONMAN 70.3.	Chattanooga, TN	Tennessee River, Mile 462.7–467.5 (Tennessee).
18. 2 days- Saturday and Sunday before Memorial Day.	Powerboat Nationals-Point Marion	Point Marion, PA	Monongahela River, Miles 89.0–91.0 (Pennsylvania).
19. 1 day—During the last weekend in May or on Memorial Day.	Mayor's Hike, Bike and Paddle	Louisville, KY	Ohio River, Mile 601.0–604.5 (Kentucky).
20. 1 day in May	Chickamauga Dam Swim	Chattanooga, TN	Tennessee River, Mile 470.0–473.0 (Tennessee).
21. 2 days—Last weekend in May or first weekend in June.	Visit Knoxville/Racing on the Tennessee.	Knoxville, TN	Tennessee River, Mile 647.0–648.0 (Tennessee).
22. 1 day in May	Outdoor Chattanooga/Nooga Loop	Chattanooga, TN	Tennessee River, Mile 452.0–458.0 (Tennessee).
23. 2 days—First weekend of June	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Kentucky).
24. 1 day—First weekend in June	Visit Knoxville/Knoxville Powerboat Classic.	Knoxville, TN	Tennessee River, Mile 646.4–649.0 (Tennessee).
25. 3 days—One of the last three weekends in June.	Lawrenceburg Regatta/Whiskey City Regatta.	Lawrenceburg, IN	Ohio River, Mile 491.0–497.0 (Indiana).
26. 3 days—One of the last three weekends in June.	Hadi Shrine/Evansville Shriners Festival.	Evansville, IN	Ohio River, Mile 790.0–796.0 (Indiana).
27. 3 days—Third weekend in June ...	TM Thunder LLC/Thunder on the Cumberland.	Nashville, TN	Cumberland River, Mile 189.6–192.3 (Tennessee).
28. 1 day—Third or fourth weekend in June.	Greater Morgantown Convention and Visitors Bureau/Mountaineer Triathlon.	Morgantown, WV	Monongahela River, Mile 101.0–102.0 (West Virginia).
29. 1 day—A weekend in June	Team Magic/Chattanooga Waterfront Triathlon.	Chattanooga, TN	Tennessee River, Mile 462.5–466.0 (Tennessee).
30. 1 day—One weekend in June	Race on the Oyo	Racine, OH, to Point Pleasant, WV.	Ohio River Mile 242.0–265.0 (Ohio)
31. 3 days in June	Lake Guntersville Hydrofest	Guntersville, AL	Tennessee River 355.5–365.5 (Alabama)
32. 1 day in June	Music City Triathlon	Nashville, TN	Cumberland River, Mile 189.7–192.3 (Tennessee).
33. 1 Day—Last Weekend in June or first weekend in July.	Charleston Sternwheel Regatta	Charleston, WV	Kanawha River Mile 58.0–59.0 (West Virginia)
34. 3 days—The last weekend in June or one of the first two weekends in July.	Madison Regatta	Madison, IN	Ohio River, Mile 554.0–561.0 (Indiana).
35. 1 Day in July	Three Rivers Regatta	Knoxville, TN	Tennessee River, Mile 642–653 (Tennessee)
36. 1 Day in July	Tri-Louisville	Louisville, KY	Ohio River, Mile 600.5–604.0 (Kentucky).
37. 1 Day in July	PADL	Cannelton, IN	Ohio River, Miles 719.0–727.0 (Kentucky)
38. 1 day—First week in July	Cincinnati Parks-Sawyer Point/Cincinnati Parks Board.	Cincinnati, OH	Ohio River, Miles 469–470 (Ohio)

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio Valley location	Regulated area
39. 1 day—First week in July	City of New Richmond, Riverdays/ VFW.	New Richmond, OH ...	Ohio River, Mile 449.5—450.5 (Ohio)
40. 1 day—During the first week of July.	Evansville Freedom Celebration/4th of July Freedom Celebration.	Evansville, IN	Ohio River, Mile 790.0—797.0 (Indiana).
41. First weekend in July	Eddyville Creek Marina/Thunder Over Eddy Bay.	Eddyville, KY	Cumberland River, Mile 46.0—47.0 (Kentucky).
42. 2 days—One of the first two week- ends in July.	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Ken- tucky).
43. 1 day—Second weekend in July ...	Bradley Dean/Renaissance Man Triathlon.	Florence, AL	Tennessee River, Mile 254.0—258.0 (Alabama).
44. 2 days—Second weekend in July	New Martinsville Vintage Regatta	New Martinsville, WV ..	Ohio River Mile 127.5—128.5 (West Virginia).
45. 1 day—Third or fourth Sunday of July.	Tucson Racing/Cincinnati Triathlon ...	Cincinnati, OH	Ohio River, Mile 468.3—471.2 (Ohio).
46. 2 days—One of the last three weekends in July.	Dare to Care/KFC Mayor's Cup Pad- dle Sports Races/Voyageur Canoe World Championships.	Louisville, KY	Ohio River, Mile 600.0—605.0 (Ken- tucky).
47. 2 days—Last two weeks in July or first three weeks of August.	Friends of the Riverfront Inc./Pitts- burgh Triathlon and Adventure Races.	Pittsburgh, PA	Allegheny River, Mile 0.0—1.5 (Penn- sylvania).
48. 1 day—Last weekend in July	Maysville Paddlefest	Maysville, KY	Ohio River, Mile 408—409 (Kentucky)
49. 2 days—One weekend in July	Marietta Riverfront Roar Regatta	Marietta, OH	Ohio River, Mile 171.6—172.6 (Ohio).
50. 1 day in August	Three Rivers Regatta	Knoxville, TN	Tennessee River 642.0—653.0 (Ten- nessee)
51. 1 day in August	K-Town On The River	Knoxville, TN	Tennessee River 648—650 (Ten- nessee)
52. 1 day—first Sunday in August	Above the Fold Events/Riverbluff Triathlon.	Ashland City, TN	Cumberland River, Mile 157.0—159.5 (Tennessee).
53. 3 days—First week of August	EQT Pittsburgh Three Rivers Regatta	Pittsburgh, PA	Allegheny River mile 0.0—1.0, Ohio River mile 0.0—0.8, Monongahela River mile 0.5 (Pennsylvania).
54. 2 days—First weekend of August	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Ken- tucky).
55. 1 day—in August	Riverbluff Triathlon	Ashland City, TN	Cumberland River, Mile 157.0—159.0 (Tennessee).
56. 1 day—In august	Team Rocket Tri Club/Swim Hobbs Island.	Huntsville, AL	Tennessee River, Mile 332.3—338.0
57. 1 Day- In August	Team Rocket Tri-Club/Rocketman Triathlon.	Huntsville, AL	Tennessee River, Mile 332.2—335.5 (Alabama).
58. 1 day—One of the first two week- ends in August.	Adventure Crew/Ohio River Paddlefest.	Cincinnati, OH	Ohio River, Mile 464.5—477 (Ohio and Kentucky).
59. 2 days—Third full weekend (Satur- day and Sunday) in August.	Ohio County Tourism/Rising Sun Boat Races.	Rising Sun, IN	Ohio River, Mile 504.0—508.0 (Indiana and Kentucky).
60. 3 days—Second or Third weekend in August.	Kittanning Riverbration Boat Races ...	Kittanning, PA	Allegheny River mile 42.0—46.0 (Pennsylvania).
61. 3 days—One of the last two week- ends in August.	Thunder on the Green	Livermore, KY	Green River, Mile 69.0—72.5 (Ken- tucky).
62. 1 day in August	Tennessee Clean Water Network/ Downtown Dragon Boat Races.	Knoxville, TN	Tennessee River, Mile 646.3—648.7 (Tennessee).
63. 2 days—One weekend in August	POWERBOAT NATIONALS— Ravenswood Regatta.	Ravenswood, WV	Ohio River, Mile 220.5—221.5 (West Virginia).
64. 2 days—One weekend in August	Powerboat Nationals-Parkersburg Re- gatta/Parkersburg Homecoming.	Parkersburg, WV	Ohio River Mile 183.5—285.5 (West Virginia).
65. 2 Days in August	Ironman Triathlon	Louisville, KY	Ohio River, Mile 600.5—605.5 (Ken- tucky)
66. 3 days—One weekend in August	Grand Prix of Louisville	Louisville, KY	Ohio River, Mile 601.0—605.0 (Ken- tucky).
67. 3 days—One weekend in August	Evansville HydroFest	Evansville, IN	Ohio River, Mile 790.5—794.0 (Indi- ana).
68. 3 days—One weekend in the month of August..	Owensboro HydroFair	Owensboro, KY	Ohio River, Mile 794.0—760.0 (Ken- tucky).
69. 1 day—First or second weekend of September.	SUP3Rivers The Southside Outside ..	Pittsburgh, PA	Monongahela River mile 0.0—3.09 Al- legheny River mile 0.0—0.6 (Penn- sylvania).
70. 1 day—First weekend in Sep- tember or on Labor Day.	Mayor's Hike, Bike and Paddle	Louisville, KY	Ohio River, Mile 601.0—610.0 (Ken- tucky).
71. 2 days—Sunday before Labor Day and Labor Day.	Cincinnati Bell, WEBN, and Proctor and Gamble/Riverfest.	Cincinnati, OH	Ohio River, Mile 463.0—477.0 (Ken- tucky and Ohio) and Licking River Mile 0.0—3.0 (Kentucky).
72. 2 days—Labor Day weekend	Wheeling Vintage Race Boat Associa- tion Ohio/Wheeling Vintage Regatta.	Wheeling, WV	Ohio River, Mile 90.4—91.5 (West Vir- ginia).

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio Valley location	Regulated area
73. 3 days- The weekend of Labor Day.	Portsmouth River Days	Portsmouth, OH	Ohio River, Mile 355.5- 356.8 (Ohio)
74. 2 days—One of the first three weekends in September.	Louisville Dragon Boat Festival	Louisville, KY	Ohio River, Mile 602.0–604.5 (Kentucky).
75. 2 days—One of the first three weekends in September.	State Dock/Cumberland Poker Run ...	Jamestown, KY	Lake Cumberland (Kentucky).
76. 3 days—One of the first three weekends in September.	Fleur de Lis Regatta	Louisville, KY	Ohio River, Mile 594.0.0–598.0 (Kentucky).
77. 1 day in September	City of Clarksville/Riverfest	Clarksville, TN	Cumberland River, Mile 125.0–126.0 (Tennessee).
78. 3 days in September	Music City Grand Prix	Nashville, TN	Cumberland River 190–191 (Tennessee)
79. 1 day—One Sunday in September	Ohio River Sternwheel Festival Committee Sternwheel race reenactment.	Marietta, OH	Ohio River, Mile 170.5–172.5 (Ohio).
80. 1 Day—One weekend in September.	Parkeburg Paddle Fest	Parkersburg, WV	Ohio River, Mile 184.3–188 (West Virginia).
81. 2 days—One of the last three weekends in September.	Madison Vintage Thunder	Madison, IN	Ohio River, Mile 556.5–559.5 (Indiana).
82. 1 day—Third Sunday in September.	Team Rocket Tri Club/Swim Hobbs Island.	Huntsville, AL	Tennessee River, Mile 332.3–338.0 (Alabama).
83. 1 day in September	Knoxville Open Water Swimmers/ Bridges to Bluffs.	Knoxville, TN	Tennessee River, Mile 641.0–648.0 (Tennessee).
84. 1 Day- Last Sunday in August or Second Sunday in September.	Adventure Crew/Great Ohio River Swim.	Cincinnati, OH	Ohio River, Mile 468.8–471.2 (Ohio and Kentucky).
85. 1 day—One of the last two weekends in September.	Ohio River Open Water Swim	Prospect, KY	Ohio River, Mile 587.0–591.0 (Kentucky).
86. 2 days—One of the last three weekends in September or the first weekend in October.	Captain Quarters Regatta	Louisville, KY	Ohio River, Mile 594.0–598.0 (Kentucky).
87. 3 days—One of the last three weekends in September or one of the first two weekends in October.	Owensboro Air Show	Owensboro, KY	Ohio River, Mile 754.0–760.0 (Kentucky).
88. 1 day in September	World Triathlon Corporation/ IRONMAN Chattanooga.	Chattanooga, TN	Tennessee River, Mile 462.7–467.5 (Tennessee).
89. 3 days—Last weekend of September and/or first weekend in October.	New Martinsville Records and Regatta Challenge Committee.	New Martinsville, WV	Ohio River, Mile 128–129 (West Virginia).
90. 2 days—First weekend of October	Three Rivers Rowing Association/ Head of the Ohio Regatta.	Pittsburgh, PA	Allegheny River mile 0.0–5.0 (Pennsylvania).
91. 1 day in October	Chattajack	Chattanooga, TN	Tennessee River, Miles 462.7–465.5 (Tennessee).
92. 1 day in October	Cumberland River Compact/Cumberland River Dragon Boat Festival.	Nashville, TN	Cumberland River, Mile 189.7–192.1 (Tennessee).
93. 1 day in October	Outdoor Chattanooga/Swim the Suck	Chattanooga, TN	Tennessee River, Miles 443–455 (Tennessee).
94. 1 day in October	Lookout Rowing Club/Chattanooga Head Race.	Chattanooga, TN	Tennessee River, Mile 463.0–468.0 (Tennessee).
95. 1 day in October	Shoals Scholar Dollar	Florence, AL	Tennessee River 255–257 (Alabama)
96. 2 days in October	Music City Head Race	Nashville, TN	Cumberland River 190–195 (Tennessee)
97. 2 days—First or second week of October.	Head of the Ohio Rowing Race	Pittsburgh, PA	Allegheny River, Mile 0.0–3.0 (Pennsylvania).
98. 2 days—in October	Oak Ridge Rowing Association/Secret City Head Race Regatta.	Oak Ridge, TN	Clinch River, Mile 46.0–54.0 (Tennessee)
99. 3 days—a weekend in November	Head of the Hooch Regatta	Chattanooga, TN	Tennessee River, Mile 463.0–468.0 (Tennessee).
100. 1 day—Second weekend in December.	Charleston Lighted Boat Parade	Charleston, WV	Kanawha River, Mile 54.3–60.3 (West Virginia).

* * * * *

Dated: February 12, 2024.

H.R. Mattern,*Captain, U.S. Coast Guard, Captain of the Port, Sector Ohio Valley.*

[FR Doc. 2024–03235 Filed 2–15–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165****[Docket No. USCG–2024–0087]****Security Zone; Potomac River and Anacostia River, and Adjacent Waters; Washington, DC****AGENCY:** Coast Guard, Department of Homeland Security (DHS).**ACTION:** Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a security zone along the Potomac River, the Anacostia River, and adjacent waters at Washington, DC, for activities associated with the U.S. President's State of the Union Address. The zone will be enforced on March 7, 2024, through the early morning hours of March 8, 2024. During the enforcement period, entry into, or remaining within the zone is prohibited unless authorized by the Captain of the Port or his designated representative.

DATES: The regulations in 33 CFR 165.508 will be enforced from 9 a.m. on March 7, 2024, until 2 a.m. on March 8, 2024, for the security zone locations identified in 33 CFR 165.508(a)(6).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LTJG Ausley, U.S. Coast Guard Sector Maryland-National Capital Region (Waterways Management Division); telephone 410–576–2519, email navin.m.ausley@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce regulations in 33 CFR 165.508 for the security zone locations identified in paragraph (a)(6) from 9 a.m. on March 7, 2024, to 2 a.m. on March 8, 2024. This action is being taken to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after the U.S. President's State of the Union Address before a Joint Session of Congress. Our regulations for the Security Zone; Potomac River and Anacostia River, and adjacent waters; Washington, DC, § 165.508(a)(6), specifies the location for this security zone as an area that includes all navigable waters described in paragraphs (a)(1) through (a)(3), which includes Zones 1, 2, and 3.

- Security Zone 1, paragraph (a)(1); all navigable waters of the Potomac River, from shoreline to shoreline,

bounded to the north by the Francis Scott Key (US–29) Bridge, at mile 113, and bounded to the south by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51'21.3" N, 077°02'00.0" W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51'24.3" N, 077°01'19.8" W, including the waters of the Boundary Channel, Pentagon Lagoon, Georgetown Channel Tidal Basin, and Roaches Run.

- Security Zone 2, paragraph (a)(2); all navigable waters of the Anacostia River, from shoreline to shoreline, bounded to the north by the John Philip Sousa (Pennsylvania Avenue) Bridge, at mile 2.9, and bounded to the south by a line drawn from the District of Columbia shoreline at Hains Point at position 38°51'24.3" N, 077°01'19.8" W, southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50'52.4" N, 077°01'10.9" W, including the waters of the Washington Channel.

- Security Zone 3 paragraph (a)(3); all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51'21.3" N, 077°02'00.0" W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51'24.3" N, 077°01'19.8" W, thence southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50'52.4" N, 077°01'10.9" W, and bounded to the south by the Woodrow Wilson Memorial (I–95/I–495) Bridge, at mile 103.8.

During the enforcement period, as specified in § 165.508(b), entry into or remaining in these zones is prohibited unless authorized by the Coast Guard Captain of the Port Maryland-National Capital Region. Public vessels and vessels already at berth at the time the security zone is implemented do not have to depart the security zone. All vessels underway within the security zone at the time it is implemented are to depart the zone at the time the security zone is implemented. To seek permission to transit the zone, the Captain of the Port Maryland-National Capital Region can be contacted at telephone number (410) 576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing this zone can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation. If the Captain

of the Port or his designated on-scene patrol personnel determines the security zone need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to suspend enforcement and grant general permission to enter the security zone.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

Dated: February 13, 2024.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2024–03298 Filed 2–15–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165****[Docket Number USCG–2024–0040]****RIN 1625–AA00****Emergency Safety Zone; Pacific Ocean, Bodega Bay, CA****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Pacific Ocean near Bodega Bay, CA in support of pollution response operations for the vessel ALEUTIAN STORM from February 13, 2024, to February 19, 2024. Based on this information, this safety zone is necessary to protect vessels and the marine environment from potential hazards associated with pollution response operations. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission from the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective without actual notice from February 16, 2024, through 11:59 p.m. February 19, 2024. For the purposes of enforcement, actual notice will be used from February 13, 2024, through February 16, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0040 in the search box and click “Search.” Next, in the Document Type

column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT William Harris, U.S. Coast Guard Sector San Francisco, Waterways Management Division; at telephone (415) 399-7443, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard identified active pollution stemming from the aground vessel ALEUTIAN STORM on February 12, 2024, and immediate action is necessary to respond to the pollution threat. It is impracticable to go through the full rulemaking process, including a reasonable comment period and consideration, because the Coast Guard must establish this emergency temporary safety zone by February 13, 2024.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to protect persons, vessels, and the marine environment involved in pollution response operations at the vessel ALEUTIAN STORM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector San Francisco (COTP) has determined that potential hazards associated with pollution response operations starting February 13, 2023, will be a safety concern for anyone within a 1,100-yard radius seaward of the vessel ALEUTIAN

STORM at coordinates 38°19'43" N 123°4'16.2" W (NAD 83). This rule is needed to protect persons, vessels, and the marine environment in the navigable waters within the safety zone during pollution response operations.

IV. Discussion of the Rule

This rule establishes a temporary safety 1,100-yard safety zone in the navigable waters of the Pacific Ocean seaward of coordinates 38°19'43" N 123°4'16.2" W (NAD 83) from 11:30 a.m. on February 13, 2024, to 11:59 p.m. on February 19, 2024, or as announced by Broadcast Notice to Mariners. The effect of the temporary safety zone will be to restrict vessel navigation in this area until the Captain of the Port San Francisco (COTP) determines that the hazards associated with the pollution response operations for the vessel ALEUTIAN STORM are no longer present. Except for persons or vessels authorized by the Captain of the Port or a designated representative, no vessel may enter or remain in the restricted area. A “designated representative” means a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the navigable waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified to ensure the safety zone will result in minimum impact. The vessels

desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP’s designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132,

Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than a week during hours that will prohibit entry within 1,100 yards of pollution response operations at the vessel ALEUTIAN STORM. It is categorically excluded from further review under paragraph L60(c) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to

coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.3.

■ 2. Add § 165.T11–158 to read as follows:

§ 165.T11–158 Emergency Safety Zone; Pacific Ocean, Bodega Bay, CA

(a) *Location.* The following area is a safety zone: all navigable waters, from surface to bottom, within a 1,100-yard radius seaward of the following coordinates 38°19'43" N 123°4'16.2" W (NAD 83).

(b) *Definitions.* As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulation in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP’s designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP’s designated representative to obtain permission to do so. Vessel operators given permission to enter or operate within the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative. Persons and vessels may request permission to enter the safety zone through the 24-hour Command Center at telephone (415) 399–3432.

(d) *Enforcement period.* This section will be enforced from 11:30 a.m. on February 13, 2024, to 11:59 p.m. on February 19, 2024, or as announced via Broadcast Notice to Mariners.

(e) *Information Broadcasts.* The COTP or the COTP’s designated representative will notify the maritime community of periods during which this zone will be enforced in accordance with 33 CFR 165.7.

Dated: February 13, 2024.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port Sector San Francisco.

[FR Doc. 2024–03369 Filed 2–14–24; 4:15 pm]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Part 5

RIN 1880–AA84

[Docket ID ED–2008–OM–0011]

Availability of Information to the Public; Correction

AGENCY: Office of the Secretary, Department of Education.

ACTION: Final rule; correction.

SUMMARY: On June 14, 2010, the Department of Education (Department) published in the **Federal Register** a final rule amending the Department’s Freedom of Information Act (FOIA) regulations, and a correction was published in the **Federal Register** on January 26, 2024. The 2010 final rule implemented amendments made to the FOIA statute and clarified how the Department processes FOIA requests for agency records, and the January 26, 2024, document corrected the administrative exhaustion provisions related to the Appeals of Adverse Determinations section in the FOIA regulations. We are correcting the title of that revised provision, which inadvertently was omitted in the January 26, 2024 correction. All other provisions in the FOIA regulations remain the same.

DATES: This correction is effective February 16, 2024.

FOR FURTHER INFORMATION CONTACT: Deborah O. Moore, Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: (202) 381–1414. Email: Deborah.Moore@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: On June 14, 2010, the Department published a

final rule amending the Department's FOIA regulations in 34 CFR part 5, including § 5.40(b) (Appeals of Adverse Determinations). On January 26, 2024, we corrected that provision to strike the last sentence, which contained erroneous language. 89 FR 5097. Because the title of the corrected provision inadvertently was omitted in the amendatory instructions, we are correcting that provision to add back the original title, "Appeal requirements."

All other information in the 2010 final rule remains the same, except for the provisions that were amended on December 12, 2019 (84 FR 67865) and January 26, 2024 (89 FR 5097).

Waiver of Rulemaking

Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, the APA provides that an agency is not required to conduct notice-and-comment rulemaking when the agency, for good cause, finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B)).

Rulemaking is "unnecessary" in those situations in which "the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public." *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001), quoting U.S. Department of Justice, *Attorney General's Manual on the Administrative Procedure Act* 31 (1947) and *South Carolina v. Block*, 558 F. Supp. 1004, 1016 (D.S.C. 1983).

There is good cause to waive rulemaking here, because rulemaking is unnecessary. The actions in this document merely correct an inadvertent deletion of an existing regulatory title and are not an exercise of the Department's discretion. Thus, the Secretary has determined that publication of a proposed rule is unnecessary under 5 U.S.C. 553(b)(B).

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official

edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Part 5

Administrative practice and procedure, Investigations.

Accordingly, part 5 of title 34 of the Code of Federal Regulations is corrected by making the following correcting amendments:

PART 5—AVAILABILITY OF INFORMATION TO THE PUBLIC

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552, 20 U.S.C. 1221e–3, and 20 U.S.C. 3474.

■ 2. Section 5.40 is amended by adding a subject heading to paragraph (b) to read as follows:

§ 5.40 Appeals of adverse determinations.

* * * * *

(b) *Appeal requirements.* * * *

* * * * *

Alexis Barrett,

Chief of Staff, Office of the Secretary
Department of Education.

[FR Doc. 2024–03267 Filed 2–15–24; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2023–0199; FRL–10830–03–R7]

Approval of State Plans for Designated Facilities and Pollutants; MO; Approval and Promulgation of Implementation Plans; Control of Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the Missouri State Implementation Plan (SIP) related to municipal solid waste landfills in the St. Louis ozone nonattainment area. The revision to this rule includes incorporating by reference Emission Guidelines (EG) for Municipal Solid Waste (MSW) landfills. EPA is approving this SIP revision based on EPA's finding that the rule implements more stringent thresholds and do not impact the stringency of the SIP or have an adverse effect on air quality. The EPA's approval of this rule revision is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective March 18, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2023–0199. 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, *i.e.*, 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 information.

FOR FURTHER INFORMATION CONTACT:

Allyson Prue, Environmental Protection Agency, Region 7 Office, Air Permitting and Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7277; email address: prue.allyson@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document "we," "us," and "our" refer to EPA.

Table of Contents

- I. Background
- II. What is being addressed in this document?
- III. Have the requirements for approval of a SIP revision been met?
- IV. The EPA's Response to Comments
- V. What action is the EPA taking?
- VI. Incorporation by Reference
- VII. Statutory and Executive Order Reviews

I. Background

On August 21, 2023, the EPA proposed to approve Missouri's submitted section 111(d) State Plan with two accompanying state rule revisions and a SIP revision in the **Federal Register** (88 FR 56787). The EPA proposed to approve both the section 111(d) State Plan with two

accompanying state rule revisions and SIP revision together. In this action, the EPA is finalizing approval of the revision to 10 CSR 10–5.490 “Municipal Solid Waste Landfills” (which covers the St. Louis area) into Missouri’s SIP. The EPA will act on the section 111(d) State Plan and the revision to 10 CSR 10–6.310 “Restriction of Emissions From Municipal Solid Waste Landfills” in a separate action.

The proposed rule includes additional background information on Missouri’s Municipal Solid Waste Landfill Rule for the St. Louis Ozone Nonattainment Area. The Technical Support Document (TSD), located in the docket for this rulemaking, includes the summary and analysis of Missouri’s SIP Revision. The EPA solicited comments on the proposed approval of the submission and received one comment.

II. What is being addressed in this document?

As part of this action, EPA is approving the revision to 10 CSR 10–5.490, which implements the 2016 MSW landfill EG at more stringent thresholds in the St. Louis ozone nonattainment area, into Missouri’s SIP. EPA’s approval of 10 CSR 10–5.490 is in accordance with section 110 of the CAA and 40 CFR part 51.

EPA’s detailed rationale and discussion of Missouri’s revisions to 10 CSR 10–5.490 can be found in the EPA TSD, located in the docket for this rulemaking.

III. Have the requirements for approval of a SIP revision been met?

The State’s submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from December 27, 2021 to February 3, 2022 and held a public hearing on January 27, 2022. The State received one comment on 10 CSR 10–5.490 concerning incorporation by reference of federal requirements and modified the rule in response.

In addition, as explained above and in more detail in the technical support document (TSD) which is part of this docket, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

IV. The EPA’s Response to Comments

The public comment period on the EPA’s proposed rule opened August 21, 2023 the date of its publication in the **Federal Register** and closed on

September 20, 2023. During this period, EPA received one comment from an individual commenter that was supportive of EPA’s proposed action.

V. What action is the EPA taking?

The EPA is taking final action to approve Missouri’s SIP revision submitted by the MoDNR on July 25, 2022 revising Missouri state rule 10 CSR 10–5.490, which incorporates requirements established in EPA’s updated Emission Guidelines, into the Missouri SIP replacing the prior SIP-approved version of the state rule. EPA amends 40 CFR part 52, subpart AA, to reflect this action.

VI. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Missouri state rule 10 CSR 10–5.490, state effective date July 30, 2022, which regulates municipal solid waste landfills in the St. Louis area as set forth below in the amendments to 40 CFR part 52. EPA has made, and will continue to make, these materials generally available through the docket for this action, EPA–R07–OAR–2023–0199, at <https://www.regulations.gov> and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

Therefore, these materials have been approved by the EPA for inclusion in the State Implementation Plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 minimum criteria of the CAA. 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); and

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP submission is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address

“disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. 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.” 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.”

MoDNR did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of

the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2). Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 16, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting

and recordkeeping requirements, Volatile organic compounds.

Dated: February 12, 2024.

Meghan A. McCollister,
Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

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 AA—Missouri

■ 2. In § 52.1320, the table in paragraph (c) is amended by revising the entry for “10–5.490” to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
* * *	* * *	* * *	* * *	* * *
Chapter 5—Air Quality Standards and Air Pollution Control Regulations for the St. Louis Metropolitan Area				
* * *	* * *	* * *	* * *	* * *
10–5.490	Municipal Solid Waste Landfills.	July 30, 2022	2/16/2024, [insert Federal Register citation].	
* * *	* * *	* * *	* * *	* * *

* * * * *

[FR Doc. 2024–03299 Filed 2–15–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2023–0299; EPA–HQ–OLEM–2023–00304; EPA–HQ–OLEM–2023–0382; FRL–11238–02–OLEM]

Deletion From the National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of one site and partially deletion of two sites from the Superfund National

Priorities List (NPL). The NPL, created under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the States, through their designated State agencies, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: The document is effective February 16, 2024.

ADDRESSES: *Docket:* EPA has established a docket for this action under the Docket Identification included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. All documents in the docket are listed on the [https://](https://www.regulations.gov)

www.regulations.gov website. The Final Close-Out Report (FCOR, for a full site deletion) or the Partial Deletion Justification (PDJ, for a partial site deletion) is the primary document which summarizes site information to support the deletion. It is typically written for a broad, non-technical audience and this document is included in the deletion docket for each of the sites in this rulemaking. Although listed in the index, some information is not publicly available, *i.e.*, 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. Docket materials are available through <https://www.regulations.gov> or at the corresponding Regional Records Centers. Locations, addresses, and

phone numbers of the Regional Records Center follows.

- Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA New England, SEMS Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; 617/918–1440.

- Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; 212/637–4308.

- Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street SW, Mail code 9T25, Atlanta, GA 30303.

- EPA Headquarters Docket Center Reading Room (deletion dockets for all States), William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004, (202) 566–1744.

EPA staff listed below in the **FOR FURTHER INFORMATION CONTACT** section may assist the public in answering inquiries about deleted sites, accessing deletion support documentation, and determining whether there are

additional physical deletion dockets available.

FOR FURTHER INFORMATION CONTACT:

- Robert Lim, U.S. EPA Region 1 (CT, ME, MA, NH, RI, VT), lim.robert@epa.gov, 617–918–1392.

- Mabel Garcia, U.S. EPA Region 2 (NJ, NY, PR, VI), garcia.mabel@epa.gov, 212–637–4356.

- Leigh Lattimore, U.S. EPA Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), lattimore.leigh@epa.gov, 404–562–8768.

- Charles Sands, U.S. EPA Headquarters, sands.charles@epa.gov, 202–566–1142.

SUPPLEMENTARY INFORMATION: The NPL, created under section 105 of CERCLA, as amended, is an appendix of the NCP. The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. Partial deletion of sites is in accordance with 40 CFR 300.425(e) and are consistent with the Notice of

Policy Change: Partial Deletion of Sites Listed on the National Priorities List, 60 FR 55466, (November 1, 1995). The sites to be deleted are listed in Table 1, including docket information containing reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete. The NCP permits activities to occur at a deleted site, or that media or parcel of a partially deleted site, including operation and maintenance of the remedy, monitoring, and five-year reviews. These activities for the site are entered in Table 1 in this **SUPPLEMENTARY INFORMATION** section, if applicable, under Footnote such that; 1 = site has continued operation and maintenance of the remedy, 2 = site receives continued monitoring, and 3 = site five-year reviews are conducted. As described in 40 CFR 300.425(e)(3) of the NCP, a site or portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

TABLE 1

Site name	City/county, state	Type	Docket No.	Footnote
Portsmouth Naval Shipyard	Kittery, ME	Full	EPA-HQ-OLEM-2023-0382	1, 2, 3.
Universal Oil Products (Chemical Division)	East Rutherford, NJ	Partial	EPA-HQ-OLEM-2023-0304.	
Tyndall Air Force Base	Panama City, FL	Partial	EPA-HQ-OLEM-2023-0299	1, 3.

Information concerning the sites to be deleted and partially deleted from the NPL, and the proposed rule for the

deletion and partial deletion of the sites, are included in Table 2.

TABLE 2

Site name	Date, proposed rule	FR citation	Full site deletion (full) or media/parcels/description for partial deletion
Portsmouth Naval Shipyard	8/16/2023	88 FR 55611	Full.
Universal Oil Products (Chemical Division)	8/16/2023	88 FR 55611	Partial, 17 acres of soil from OU1.
Tyndall Air Force Base	8/16/2023	88 FR 55611	Partial, OUs 10, 11 and parts of 15 and 25.

For the sites proposed for deletion, the closing date for comments in the proposed rule was September 15, 2023. The EPA received no public comments for any of the three sites in this final rule. The deletion criteria for the Site have been met, and detailed information is available on <https://www.regulations.gov>, and in the appropriate Regional Records Centers listed in the **ADDRESSES**.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the

NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping

requirements, Superfund, Water pollution control, Water supply.

Larry Douchand,

Office Director, Office of Superfund Remediation and Technology Innovation.

For reasons set out in the preamble, the EPA amends 40 CFR part 300 as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*; 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757,

3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. In Appendix B to part 300, amend Table 1 by:

■ a. Revising the entry for “NJ”, “Universal Oil Products (Chemical Division)”, “East Rutherford”.
The revisions read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes (a)
NJ	Universal Oil Products (Chemical Division)	East Rutherford	P.

* P = Sites with partial deletion(s).

Table 2—[Amended]

■ 3. In Appendix B to part 300, amend Table 2 by:

■ a. Removing the entry for “ME”, “Portsmouth Naval Shipyard”, “Kittery”.

[FR Doc. 2024–03003 Filed 2–15–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 723

[EPA–HQ–OPPT–2021–0419; FRL–11729–01–OCSPP]

RIN 2070–AK68

Toxic Substances Control Act (TSCA) Requirements for Polymer Exemption Reports and Accompanying Claims; Extension of the Reporting Deadline for 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the Toxic Substances Control Act (TSCA) regulations for polymers manufactured under the terms of the polymer exemption by extending the submission deadline for reporting. The regulations require that manufacturers (includes importers) of polymers manufactured under the terms of the exemption submit a report of manufacture or import by January 31 of the year subsequent to initial manufacture. On June 7, 2023, EPA amended the exemption reporting requirement to require that the exemption report and accompanying confidentiality claims be submitted electronically. Because EPA experienced technical difficulties with the launch of the new electronic reporting tool, EPA is extending the reporting period for 2024 from January 31 to March 31 to allow manufacturers

additional time to submit their reports and accompanying claims to EPA using the electronic reporting tool.

DATES: This final rule is effective on February 16, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0419, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Loraine Passe, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9064; email address: passe.loraine@epa.gov.

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you were a manufacturer or importer of a polymer under the terms of the polymer exemption in 2023. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical Manufacturers (NAICS code 325).
- Petroleum and Coal Products (NAICS code 324).
- Merchant Wholesalers, Nondurable Goods (NAICS code 424).

This list details the types of entities that EPA is aware could potentially be regulated by this action. Other types of entities not listed could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR 723.250. If you have questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency’s authority for taking this action?

EPA is promulgating this rule pursuant to its authority in TSCA section 5 (15 U.S.C. 2604). In addition, section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that an agency may issue a final rule without a prior proposal if it finds for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

C. What action is the Agency taking?

EPA is extending the reporting deadline for polymer exemption reports under 40 CFR 723.250 for this year for exemption reports and accompanying claims from January 31 to March 31. EPA believes this extension will provide reporters with sufficient time to submit information using the electronic reporting tool and for EPA to fix any unanticipated glitches that may arise with the use of the new tool.

D. Why is this issued as a final rule?

Pursuant to section 553(b)(B) of the APA (5 U.S.C. 553(b)(B)), EPA has determined that there is good cause for extending the reporting deadline for 2024 without prior proposal and opportunity for comment. EPA encountered technical issues when launching a new polymer exemption electronic reporting tool and the time to fix those issues took longer than

expected. As a result, it was not possible for manufacturers to submit their required reports and accompanying claims electronically until January 29, 2024, three business days before the January 31st regulatory due date for 2024. EPA determines that there is good cause to take this action without a prior proposal because it would be contrary to the public interest to retain the deadline of January 31 for the 2024 reports, where EPA's electronic systems were not ready and available for use by regulated entities to allow them to comply with the electronic reporting requirements of the rule before the submission deadline of January 31, 2024.

Moreover, EPA previously provided notice that if technical issues with electronic reporting of polymer exemption reports occurred, it would make appropriate accommodations such as extending reporting deadlines. The issue was discussed in the preamble to the final rule establishing the electronic reporting deadline in question (88 FR 37155, June 7, 2023 (FRL-8223-02-OCSPP)), which became effective on August 7, 2023, and required the use of a new electronic reporting tool for submitting annual polymer exemption reports and accompanying claims. That rule amended the regulations in 40 CFR 723.250(f) to state, “. . . The report and accompanying claims must be submitted via CDX (<https://cdx.epa.gov/>), using the TSCA Section 5 Notices and Supports—ePMN application.” In that rule, EPA responded to several commenters that expressed concern over reliance on electronic reporting, citing past incidences of technical difficulties with providing electronic submissions via CDX. Specifically, EPA responded in that final rule that it did not expect issues with electronic reporting of polymer exemption reports, but if such issues did occur the Agency would continue its practice of promptly addressing problems and, “. . . making appropriate accommodations (such as extending reporting deadlines)” (88 FR 37155, June 7, 2023 (FRL-8223-02-OCSPP)). EPA did not anticipate the technical issues it had with launching the tool and expected the new reporting tool to be fully functional well ahead of the January 31st reporting deadline. Unfortunately, the tool only became functional three business days before the January 31, 2024, deadline. As EPA had already acknowledged that it could extend reporting deadlines if technical issues with the reporting tool arose, providing further notice and public procedure would serve no purpose and is unnecessary.

APA section 553(d) (5 U.S.C. 553(d)), in turn, allows an agency to make a rule immediately effective “for good cause found and published with the rule.” For the reasons discussed in this unit, EPA believes that there is good cause to make this amendment to codify the extension to the 2024 reporting deadline effective upon publication in the **Federal Register**.

Extending the reporting deadline for 2024 is beneficial to regulated entities that need to comply with the regulations because it provides them with more time to complete the submission using the new electronic reporting tool. This final rule has no adverse impact and does not otherwise alter the reporting and recordkeeping requirements contained in the rule.

II. 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#influence>.

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 the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not contain any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing new chemical regulations under OMB Control No. 2070-0038 (EPA ICR No. 1188.14), which was updated with the CBI revisions and electronic submission approved under OMB Control No. 2070-0223 (EPA ICR No. 2707.02). This action only delays the reporting deadline for 2024 and does not otherwise change any of the information collection activities.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This final rule action is not subject to notice and comment requirements under the APA because the Agency has invoked the APA “good cause” exemption.

D. Unfunded Mandates Reform Act (UMRA)

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of UMRA, 2 U.S.C. 1531–1538 *et seq.*

E. Executive Order 13132: Federalism

This action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) because it will not have substantial direct effects 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.

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

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern human health, EPA's 2021 Policy on Children's Health does not apply.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

This action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to the potential for disproportionate impacts on non-white and low-income populations in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023).

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Unit I.D., including the basis for that finding.

List of Subjects in 40 CFR Part 723

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 9, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 723—PREMANUFACTURE NOTIFICATION EXEMPTIONS

■ 1. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

■ 2. In § 723.250(f), revise the introductory text to read as follows:

§ 723.250 Polymers.

* * * * *

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1) through (3) of this section a report of manufacture or import must be submitted by January 31 of the year subsequent to initial manufacture, except that for initial manufacture or import in 2023 the report must be submitted by March 31,

2024. The report and accompanying claims must be submitted via CDX (<https://cdx.epa.gov/>), using the TSCA Section 5 Notices and Supports—ePMN application. See § 720.40(a)(2)(ii) of this subchapter for information on how to access e-PMN software. The notice must include:

* * * * *

[FR Doc. 2024–03064 Filed 2–15–24; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 300–3, 301–10, 301–31, 301–50, 301–51, 301–70 Through 301–76, Chapter 301, and Parts 302–1 Through 302–9, 302–11, 302–12, 302–14 Through 302–17, 303–70, 304–2, 304–3, and 304–5

[FTR Case 2022–05; Docket No. GSA–FTR–2022–0005, Sequence No. 1]

RIN 3090–AK67

Federal Travel Regulation; Updating the FTR With Diversity, Equity, Inclusion, and Accessibility Language

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: GSA is issuing a final rule that makes technical amendments to the Federal Travel Regulation (FTR) regarding gender neutrality. These technical amendments result in more inclusive language by replacing gender-specific pronouns (e.g., he, she, his, her) with non-gendered pronouns. These changes are grammatical and technical in nature and do not result in added costs or associated policy changes.

DATES: This final rule is effective on April 16, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Ed Davis, Program Analyst, Office of Government-wide Policy, at 202–669–1653 or travelpolicy@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 “FTR Case 2022–05.”

SUPPLEMENTARY INFORMATION:

I. Background

Executive Order (E.O.) 13988, *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation*, dated January 20, 2021, establishes a policy “to prevent and combat discrimination

on the basis of gender identity or sexual orientation, and to fully enforce Title VII and other laws that prohibit discrimination on the basis of gender identity or sexual orientation.”

The Federal Government must be a model for diversity, equity, inclusion, and accessibility, where all employees are treated with dignity and respect. While GSA is not aware of any specific instances where language in the FTR has been used to discriminate against an employee seeking reimbursement for travel or relocation expenses, GSA believes it is important to prevent any potential discrimination or the appearance of discrimination. Therefore, GSA has undertaken an extensive review of the FTR and is updating all instances where language used to identify individuals is not as inclusive as it could be.

Consistent with the American Psychological Association (APA) Style Guide, 7th Edition, Publication Manual Section 5.5 guidance on “Gender and Pronoun Usage”, GSA is replacing gender-specific pronouns, such as he, she, his, or her with more inclusive and respectful terminology to all segments of society. Other terms that do not use gender-specific language, such as employee, traveler, sibling, child, and parent have also been used as appropriate.

II. Waiver of Proposed Rulemaking

In developing this final rule, GSA is waiving notice of proposed rulemaking, public comment, and effective date procedures set forth in the Administrative Procedure Act, 5 U.S.C. 553 (APA). The APA provides an exception to those procedures when an agency finds there is good cause for dispensing with such procedures. See 5 U.S.C. 553(b)(3)(B), 553(d)(3). Here, GSA has determined that good cause exists for dispensing with these procedures because they are unnecessary. The removal of gender-specific language is a grammatical, technical amendment that does not change policy or require the expenditure of agency funds. It instead makes clear that the FTR should not be interpreted to condone potential gender discrimination or the appearance of gender discrimination, even if GSA is unaware of the FTR's gendered language being used to discriminate against an employee. Therefore, this rule is not subject to notice, an opportunity for public comment, or a delayed effective date, and will be final and effective upon publication.

III. Discussion of the Final Rule

A. Summary of Significant Changes

This final rule is technical in nature and does not significantly change any definition, operation or interpretation of the FTR.

B. Expected Cost Impact to the Public

No FTR benefit has been increased or decreased in any way by these technical changes to the FTR.

IV. Executive Orders 12866, 13563, and 14094

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*) directs 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 (*Improving Regulation and Regulatory Review*) emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. E.O. 14094 (*Modernizing Regulatory Review*) amends section 3(f) of E.O. 12866 and supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in E.O. 12866 and E.O. 13563. The Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) has determined that this rule is not a significant regulatory action and, therefore, it was not reviewed under Section 6(b) of E.O. 12866.

V. Congressional Review Act

Title II, subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (codified at 5 U.S.C. 801–808), also known as the Congressional Review Act or CRA, generally provides that before a rule may take effect, unless excepted, 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. This rule is excepted from CRA reporting requirements prescribed under 5 U.S.C. 801 as it relates to agency management or personnel under 5 U.S.C. 804(3)(B).

VI. Regulatory Flexibility Act

This final rule will not 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.* This

final rule is also exempt from the Administrative Procedure Act pursuant to 5 U.S.C. 553(a)(2) because it applies to agency management or personnel. Therefore, an Initial Regulatory Flexibility Analysis was not performed.

VII. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

List of Subjects in 41 CFR Parts 300–3, 301–10, 301–31, 301–50, 301–51, 301–70 Through 301–76, Appendix C to Chapter 301, 302–1 Through 302–9, 302–11, 302–12, 302–14 Through 302–17, 303–70, 304–2, 304–3, and 304–5.

Government employees, Travel and transportation expenses.

Robin Carnahan,

Administrator of General Services.

For the reasons set forth in the preamble, GSA amends 41 CFR parts 300–3, 301–10, 301–31, 301–50, 301–51, 301–70 through 301–76, Appendix C to Chapter 301, 302–1 through 302–9, 302–11, 302–12, 302–14 through 302–17, 303–70, 304–2, 304–3, and 304–5 as set forth below:

PART 300–3—GLOSSARY OF TERMS

- 1. The authority citation for part 300–3 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); 41 U.S.C. 40118; 5 U.S.C. 5738; 5 U.S.C. 5741–5742; 20 U.S.C. 905(a); 31 U.S.C. 1353; E.O. 11609, as amended, 3 CFR, 1971–1975 Comp., p. 586, Office of Management and Budget Circular No. A–126, revised May 22, 1992.

- 2. Amend § 300–3.1 by—

- a. Removing from the definition of “Commutated rate” “his/her household” and adding “their household” in its place;

- b. Removing from the definition of “Crewmember” “he/she must” and adding “that crewmember must” in its place;

- c. Removing from the definition of “Extended storage” “he/she is not” and adding “the employee is not” in its place;

- d. Removing from the introductory text of the definition of “Immediate family” “he/she reports” and adding “the employee reports” in its place; and removing from paragraph (5) “Dependent brothers and sisters (including step and legally adoptive

brothers and sisters)” and adding “Dependent siblings (including step and legally adoptive siblings)” in its place;

- e. Removing from the definition of “Official station”, in two occurrences, “his and her” and adding “their” in their places;

- f. Removing from the introductory text of the definition of “Professional Books, Papers and Equipment” the phrase “his/her official duties” and adding “the employee’s official duties” in its place; and

- g. Revising the last sentence of the definition of “Qualified non-crewmember”.

The revision reads as follows:

§ 300–3.1 What do the following terms mean?

* * * * *

Qualified non-crewmember * * * If a qualified non-crewmember is onboard for the purpose of travel (*i.e.*, being transported from point to point) in addition to performing their duties related to the non-travel related Governmental function for which the aircraft is being operated (*e.g.*, when a scientist conducts an experiment at the same time they are also on the aircraft for the purpose of traveling from point to point), they must be authorized to travel in accordance with rules in 41 CFR parts 301–10 and 301–70.

* * * * *

PART 301–10—TRANSPORTATION EXPENSES

- 3. The authority citation for part 301–10 is revised to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); 49 U.S.C. 40118; Office of Management and Budget Circular No. A–126, “Improving the Management and Use of Government Aircraft.” Revised May 22, 1992.

§ 301–10.262 [Amended]

- 4. Amend § 301–10.262 by—

- a. Removing from paragraphs (a) introductory text, (b), and (c) “his/her principal deputy” and adding “their principal deputy” in their places, respectively; and

- b. Removing from paragraph (d) “to whom he/she delegates” and adding “to whom they delegate” in its place.

PART 301–31—THREATENED LAW ENFORCEMENT/INVESTIGATIVE EMPLOYEES

- 5. The authority citation for part 301–31 continues to read as follows:

Authority: 5 U.S.C. 5707.

§ 301–31.1 [Amended]

- 6. Amend § 301–31.1 by removing “his/her immediate” and adding “the employee’s immediate” in its place.

PART 301–50—ARRANGING FOR TRAVEL SERVICES

- 7. The authority citation for part 301–50 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c).

§ 301–50.4 [Amended]

- 8. Amend § 301–50.4 by removing from the introductory text “his/her designee” and adding “their designee” in its place.

PART 301–51—PAYING TRAVEL EXPENSES

- 9. The authority citation for part 301–51 continues to read as follows:

Authority: 5 U.S.C. 5707. Subpart A is issued under the authority of Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5 U.S.C. 5701 note); 40 U.S.C. 121(c).

§ 301–51.4 [Amended]

- 10. Amend § 301–51.4 by removing “his/her designee(s)” and adding “their designee(s)” in its place.

PART 301–70—INTERNAL POLICY AND PROCEDURE REQUIREMENTS

- 11. The authority citation for part 301–70 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5 U.S.C. 5701, note); OMB Circular No. A–126, revised May 22, 1992; OMB Circular No. A–123, Appendix B, revised August 27, 2019.

§ 301–70.102 [Amended]

- 12. Amend § 301–70.102 by removing from paragraph (g) “he/she travels” and adding “the employee travels” in its place.

§ 301–70.200 [Amended]

- 13. Amend § 301–70.200 by removing from paragraphs (c) and (d) “his/her official station” and adding “their official station” in their places.

§ 301–70.700 [Amended]

- 14. Amend § 301–70.700 by removing from paragraph (c) “his/her designee” and adding “their designee” in its place.

§ 301–70.701 [Amended]

- 15. Amend § 301–70.701 by removing from paragraph (b) “his/her designee(s)” and adding “their designee(s)” in its place.

- 16. Amend § 301–70.803 by—
- a. Removing from paragraph (a) introductory text “his/her principal”

and adding “their principal” in their places;

- b. Removing from paragraph (a)(1) “his or her” and adding “their” in its place;

- c. Removing from paragraph (b) “his/her principal” and adding “their principal” in its place;

- d. Removing from paragraph (c) “his/her deputy” and adding “their deputy” in its place; and

- e. Revising paragraph (d)(1).

The revision reads as follows:

§ 301–70.803 How must we authorize travel on a Government aircraft?

* * * * *

(d) * * *

(1) Your agency’s designated travel approving official (or anyone to whom they delegate this authority and who is at least one organizational level above the traveler) must authorize, in advance and in writing, all other travel on Government aircraft (*i.e.*, by passengers, crewmembers, or qualified non-crewmembers) that is not covered in paragraphs (a) through (c) of this section.

* * * * *

- 17. Amend § 301–70.804 by—

- a. Revising paragraph (b)(1);

- b. Removing from paragraph (b)(2) “his/her dependents” and adding “the traveler’s dependents” in its place; and

- c. Removing from paragraph (c) “he/she not engaged” and adding “they not engaged” in its place.

The revision reads as follows:

§ 301–70.804 What amount must the Government be reimbursed for travel on a Government aircraft?

* * * * *

(b) * * *

(1) You must require a traveler on required-use travel to reimburse the Government for the excess of the full coach fare for all flights taken on a trip over the full coach fare for the flights that the traveler would have taken had they not engaged in personal activities during the trip; and

* * * * *

§ 301–70.901 [Amended]

- 18. Amend § 301–70.901 by removing “his/her designee” and adding “their designee” in its place.

§ 301–70.904 [Amended]

- 19. Amend § 301–70.904 by removing “he/she must present” from the text and adding “they must present” in its place.

§ 301–70.907 [Amended]

- 20. Amend § 301–70.907 by removing from paragraph (a) “he/she” and adding “the traveler” in its place.

PART 301–71—AGENCY TRAVEL ACCOUNTABILITY REQUIREMENTS

- 21. The authority citation for part 301–71 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5 U.S.C. 5701 note).

§ 301–71.200 [Amended]

- 22. Amend § 301–71.200 by removing “his/her designee” and adding “their designee” in its place.

§ 301–71.201 [Amended]

- 23. Amend § 301–71.201 by removing from the introductory text “He/she must” and adding “The reviewing official must” in its place.

§ 301–71.205 [Amended]

- 24. Amend § 301–71.205 by removing from paragraph (a) “his/her expenses” and adding “expenses” in its place.

§ 301–71.206 [Amended]

- 25. Amend § 301–71.206 by removing from paragraph (c) “he/she desires” and adding “the employee desires” in its place.

§ 301–71.208 [Amended]

- 26. Amend § 301–71.208 by removing “his/her travel” and adding “the travel” in its place.

- 27. Revise § 301–71.214 to read as follows:

§ 301–71.214 Does mandatory use of the Government contractor-issued travel charge card change the employee’s obligation to pay their travel card bill by the due date?

No, mandatory use of the Government contractor-issued travel charge card does not relieve the employee of their obligation to honor their cardholder payment agreement.

PART 301–72—AGENCY RESPONSIBILITIES RELATED TO COMMON CARRIER TRANSPORTATION

- 28. The authority citation for part 301–72 continues to read as follows:

Authority: 5 U.S.C. 5707; 31 U.S.C. 3726; 40 U.S.C. 121(c).

§ 301–72.101 [Amended]

- 29. Amend § 301–72.101 by removing from paragraph (a) “he/she is accountable” and adding “the employee is accountable” in its place.

PART 301–73—TRAVEL PROGRAMS

- 30. The authority citation for part 301–73 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c).

§ 301–73.102 [Amended]

■ 31. Amend § 301–73.102 by removing from paragraph (a) introductory text “his/her designee” and adding “their designee” in its place.

§ 301–73.103 [Amended]

■ 32. Amend § 301–73.103 by removing “his/her designee” and adding “their designee” in its place.

§ 301–73.104 [Amended]

■ 33. Amend § 301–73.104 by removing from paragraph (a) introductory text “his/her designee” and adding “the Administrator’s designee” in its place.

§ 301–73.105 [Amended]

■ 34. Amend § 301–73.105 by removing “he/she is responsible” and adding “the employee is responsible” in its place.

PART 301–74—CONFERENCE PLANNING

■ 35. The authority citation for part 301–74 continues to read as follows:

Authority: 5 U.S.C. 5707.

■ 36. Amend § 301–74.24 by revising the section heading to read as follows:

§ 301–74.24 What is the traveler required to do if they are unable to attend an event for which they were reimbursed for an advanced discounted payment of a conference or training registration fee?

* * * * *

PART 301–75—PRE-EMPLOYMENT TRAVEL

■ 37. The authority citation for part 301–75 continues to read as follows:

Authority: 5 U.S.C. 5707.

■ 38. Amend § 301–75.4 by revising paragraphs (b) and (f) to read as follows:

§ 301–75.4 What other responsibilities do we have for pre-employment interview travel?

* * * * *

(b) Inform the interviewee that the interviewee is responsible for excess cost and any additional expenses that they incur for personal preference or convenience;

* * * * *

(f) Inform the interviewee that the interviewee may subject themselves to criminal penalties if they knowingly present a false, fictitious, or fraudulent travel claim (See 18 U.S.C. 287 and 1001).

■ 39. Amend § 301–75.200 by revising the entry for “Other expenses” to read as follows:

§ 301–75.200 How will we pay for pre-employment interviewee travel expenses?

For

You will

*	*	*	*	*	*	*
Other expenses			Require payment by the interviewee and reimburse the interviewee for allowable travel expenses upon submission and approval of the interviewee’s travel claim.			

■ 40. Amend § 301–75.202 by revising the section heading and entry for “The new ticket is more expensive than the

ticket you provided” in the table to read as follows:

§ 301–75.202 What must we do if the interviewee exchanges the ticket they have been issued?

If

You will inform the traveler

The new ticket is more expensive than the ticket you provided.	That the traveler must pay the difference using personal funds and the traveler will not receive reimbursement for the extra amount.
----------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------

* * * * *

§ 301–75.205 [Amended]

■ 41. Amend § 301–75.205 by removing “he or she must” and adding “they must” in its place.

PART 301–76—COLLECTION OF UNDISPUTED DELINQUENT AMOUNTS OWED TO THE CONTRACTOR ISSUING THE INDIVIDUALLY BILLED TRAVEL CHARGE CARD

■ 42. The authority citation for part 301–76 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 121(c); Sec. 2, Pub. L. 105–264, 112 Stat. 2350 (5 U.S.C. 5701 note).

■ 43. Amend § 301–76.100 by revising paragraph (a) to read as follows:

§ 301–76.100 Are there any due process requirements with which we must comply before collecting undisputed delinquent amounts on behalf of the charge card contractor?

* * * * *

(a) Provide the employee with written notice of the type and amount of the claim, the intention to collect the claim

by deduction from the employee’s disposable pay, and an explanation of the employee’s rights as a debtor;

* * * * *

Appendix C to Chapter 301

■ 44. The authority citation for appendix C to chapter 301 continues to read as follows:

Authority: 5 U.S.C. 5707.

■ 45. Amend appendix C to chapter 301 in the table by revising the entry for “Official Station” to read as follows:

**Appendix C to Chapter 301—Standard
Data Elements for Federal Travel
[Traveler Identification]**

Group name	Data elements	Description
Official Station	City, State, Zip	The location where the employee regularly performs their duties or an invitational traveler's home or regular place of business. If the employee's work involves recurring travel or varies on a recurring basis, the location where the work activities of the employee's position of record are based is considered the employee's official station.

PART 302–1—GENERAL RULES

■ 46. The authority citation for part 302–1 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302–1.1 [Amended]

■ 47. Amend § 302–1.1 by removing from paragraph (e) “his/her place” and adding “their place” in its place.

PART 302–2—EMPLOYEE ELIGIBILITY REQUIREMENTS

■ 48. The authority citation for part 302–2 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302–2.102 [Amended]

■ 49. Amend § 302–2.102 by removing “his/her designee” and adding “their designee” in its place.

■ 50. Amend § 302–2.103 by revising paragraphs (a) and (b) to read as follows:

§ 302–2.103 How must we administer the authorization for relocation of an employee?

* * * * *

(a) Issue an employee a TA for relocation before the employee transfers to a new official station;

(b) Inform the employee of the transfer within a timeframe that will provide the employee sufficient time for preparation;

* * * * *

§ 302–2.106 [Amended]

■ 51. Amend § 302–2.106 by removing “his/her designee” and adding “their designee” in its place.

§ 302–2.110 [Amended]

■ 52. Amend § 302–2.110 by removing from the introductory text “his/her effective” and adding “the employee’s effective” in its place.

PART 302–3—RELOCATION ALLOWANCES BY SPECIFIC TYPE

■ 53. The authority citation for part 302–3 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a).

§ 302–3.1 [Amended]

■ 54. Amend § 302–3.1 by removing from paragraph (c) “his/her college” and adding “that student trainee’s college” in its place.

■ 55. Amend § 302–3.203 by revising the section heading to read as follows:

§ 302–3.203 If I am transferring in the interest of the Government and my employed immediate family member(s) transfer is not in the interest of the Government, will those immediate family member(s) receive relocation allowances?

* * * * *

§ 302–3.500 [Amended]

■ 56. Amend § 302–3.500 by—

■ a. Removing from paragraph (a) “violates his/her” and adding “violates their” in its place; and

■ b. Removing from paragraph (d) “arrange his/her” and adding “arrange their” in its place.

§ 302–3.501 [Amended]

■ 57. Amend § 302–3.501 by removing from paragraph (b) “his/her benefits” and adding “the new appointee’s benefits” in its place.

■ 58. Amend § 302–3.502 by—

■ a. Removing from paragraph (b) “his/her travel expense” and “his/her TCS expenses” and adding “the employee’s travel expense” and “their TCS expenses” in their places, respectively; and

■ b. Revising paragraph (c).

The revision reads as follows:

§ 302–3.502 What factors should we consider in determining whether to authorize a TCS for a long-term assignment?

* * * * *

(c) *Employee concerns.* The long-term assignment of an employee away from the employee’s official station and immediate family may negatively affect the employee’s morale and job performance. Such negative effects may be alleviated by authorizing a TCS so

the employee can transport their immediate family and/or household goods at Government expense to the location where the employee will perform the long-term assignment. You should consider the effects of a long-term temporary duty travel assignment on an employee when deciding whether to authorize a TCS.

§ 302–3.504 [Amended]

■ 59. Amend § 302–3.504 by removing from paragraph (e) “his/her relocation” and adding “the employee’s relocation” in its place.

■ 60. Amend § 302–3.506 by revising the section heading to read as follows:

§ 302–3.506 May we pay relocation expenses if the employee violates their service agreement?

* * * * *

§ 302–3.509 [Amended]

■ 61. Amend § 302–3.509 by—

■ a. Removing from paragraph (a) “his/her service” and adding “the service” in its place; and

■ b. Removing from paragraph (c) “his/her relocation” and adding “the employee’s relocation” in its place.

§ 302–3.510 [Amended]

■ 61. Amend § 302–3.510 by removing “his/her service” and adding “the employee’s service” in its place.

■ 62. Amend § 302–3.511 by revising paragraphs (a) and (e) to read as follows:

§ 302–3.511 What must we consider when determining return travel for immediate family member(s) for compassionate reasons prior to completion of the service agreement?

* * * * *

(a) The immediate family member(s)’ physical or mental health;

* * * * *

(e) A dependent that traveled to post of duty on the employee’s authorized TA and has now reached their 21st birthdate.

PART 302-4—ALLOWANCES FOR SUBSISTENCE AND TRANSPORTATION

- 63. The authority citation for part 302-4 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, 36 FR 13747, 3 CFR, 1971-1975 Comp., p. 586.

- 64. Revise § 302-4.203 to read as follows:

§ 302-4.203 How much per diem will my spouse or domestic partner receive if they accompany me while I am performing PCS travel?

The maximum amount your spouse or domestic partner may receive if they accompany you while you are performing PCS travel is three-fourths of your daily per diem rate.

- 65. Revise § 302-4.204 to read as follows:

§ 302-4.204 If my spouse or domestic partner does not accompany me but travels unaccompanied at a different time, what per diem rate will they receive?

If your spouse or domestic partner does not accompany you but travels unaccompanied at a different time, they will receive the same per diem rate to which you are entitled.

PART 302-5—ALLOWANCE FOR HOUSEHUNTING TRIP EXPENSES

- 66. The authority citation for part 302-5 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971-1975 Comp., p. 586.

§ 302-5.102 [Amended]

- 67. Amend § 302-5.102 by removing “his/her circumstances” and “he or she will” and adding “the employee’s circumstances” and “the employee will” in their places, respectively.

PART 302-6—ALLOWANCE FOR TEMPORARY QUARTERS SUBSISTENCE EXPENSES

- 68. The authority citation for part 302-6 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971-1975 Comp., p. 586.

§ 302-6.2 [Amended]

- 69. Amend § 302-6.2 by removing “his/her immediate family” and adding “the employee’s immediate family” in its place.

- 70. Amend § 302-6.300 by revising the first sentence to read as follows:

§ 302-6.300 How should we administer the TQSE allowance?

Temporary quarters should be used only if, and only for as long as, necessary until the employee and/or the employee’s immediate family can move into permanent residence quarters.

- 71. Amend § 302-6.303 by revising paragraph (a) to read as follows:

§ 302-6.303 What factors should we consider in determining whether the TQSE allowance is actually necessary?

(a) *The length of time the employee should reasonably be expected to occupy the employee’s residence at the old official station prior to reporting for duty at the new official station.* An employee and the employee’s immediate family should continue to occupy the residence at the old official station for as long as practicable to avoid the necessity for temporary quarters.

PART 302-7—TRANSPORTATION AND TEMPORARY STORAGE OF HOUSEHOLD GOODS, PROFESSIONAL BOOKS, PAPERS, AND EQUIPMENT, (PBP&E) AND BAGGAGE ALLOWANCE

- 72. The authority citation for part 302-7 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971-1975 Comp., p. 586.

§ 302-7.1 [Amended]

- 73. Amend § 302-7.1 by removing from paragraph (b) “his/her first” and adding “their first” in its place.

§ 302-7.201 [Amended]

- 74. Amend § 302-7.201 by removing “he/she is responsible” and adding “the employee is responsible” in its place.

PART 302-8—ALLOWANCES FOR EXTENDED STORAGE OF HOUSEHOLD GOODS (HHG)

- 75. The authority citation for part 302-8 is revised to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, 36 FR 13747, 3 CFR, 1971-1975 Comp., p. 586.

- 76. Amend § 302-8.2 by revising paragraph (b) to read as follows:

§ 302-8.2 What is the purpose of extended storage?

(b) Assigned to isolated locations in CONUS to which you cannot take or at which you are unable to use your HHG

and personal effects because of the absence of residence quarters at that location;

- 77. Amend § 302-8.402 by revising the section heading, the introductory text, and paragraph (a) to read as follows:

§ 302-8.402 May we allow the employee to determine options in the preference of the employee’s storage?

Yes, the employee may determine options in the preference of the employee’s storage. You may authorize the employee to:

(a) Transport a portion of the employee’s HHG to the official station and store the remainder at Government expense;

PART 302-9—ALLOWANCES FOR TRANSPORTATION AND EMERGENCY OR TEMPORARY STORAGE OF A PRIVATELY OWNED VEHICLE

- 78. The authority citation for part 302-9 continues to read as follows:

Authority: 5 U.S.C. 5737a; 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971-1975 Comp., p. 586.

§ 302-9.1 [Amended]

- 79. Amend § 302-9.1 by removing “his/her immediate” and adding “the employee’s immediate” in its place.

§ 302-9.602 [Amended]

- 80. Amend § 302-9.602 by removing “his/her POV” and adding “their POV” in its place.

PART 302-11—ALLOWANCES FOR EXPENSES INCURRED IN CONNECTION WITH RESIDENCE TRANSACTIONS

- 81. The authority citation for part 302-11 continues to read as follows:

Authority: 5 U.S.C. 5738 and 20 U.S.C. 905(c).

§ 302-11.106 [Amended]

- 82. Amend § 302-11.106 by removing “his/her name” and adding “that individual’s name” in its place.

- 83. Revise § 302-11.309 to read as follows:

§ 302-11.309 What residence transaction expenses are reimbursable if an employee violates the terms of the service agreement?

If the employee violates their service agreement, no residence transaction expenses will be paid, and any amounts paid prior to such violation shall be a

debt due the United States until they are paid by the employee.

§ 302–11.404 [Amended]

■ 84. Amend § 302–11.404 by removing from paragraph (e) introductory text “his/her payment” and adding “the payment” in its place and removing from paragraph (f) “his/her old” and adding “the employee’s old” in its place.

■ 85. Amend § 302–11.407 by removing from paragraph (a) “his/her financial” and adding “the employee’s financial” in its place and revising paragraph (b). The revision reads as follows:

§ 302–11.407 What documentation must we require the employee to submit before paying residence transaction expenses?

* * * * *

(b) A copy of the employee’s financial documents which prove that the employee and/or a member(s) of the immediate family received all proceeds from the sale of the property;

* * * * *

§ 302–11.421 [Amended]

■ 86. Amend § 302–11.421 by—

■ a. Removing from paragraph (a) “him/her from completing his/her” and adding “the employee from completing their” in its place; and

■ b. Removing from paragraph (b) “his/her transfer” and adding “the employee’s transfer” in its place.

■ 87. Revise § 302–11.441 to read as follows:

§ 302–11.441 How must we determine if an employee holds equitable title interest in a property?

To determine if an employee holds equitable title interest in a property, you must follow the guidelines in § 302–11.405.

PART 302–12—USE OF A RELOCATION SERVICES COMPANY

■ 88. The authority citation for part 302–12 continues to read as follows:

Authority: 5 U.S.C. 5738 and 20 U.S.C. 905(c).

§ 302–12.109 [Amended]

■ 89. Amend § 302–12.109 by removing “his/her home” and adding “their home” in its place.

■ 90. Revise § 302–12.119 to read as follows:

§ 302–12.119 Under a home sale program, may we pay an employee for losses the employee incurs on the sale of a residence?

No, under a home sale program, you may not pay an employee for losses the employee incurs on the sale of a

residence, but this does not preclude you reimbursing a relocation services company for losses incurred while the contractor holds the property.

■ 91. Revise § 302–12.120 to read as follows:

§ 302–12.120 Under a home sale program, may we direct the relocation services company to pay an employee more than the fair market value of the employee’s residence?

No, under a home sale program, you may not direct the relocation services company to pay an employee more than the fair market value (as determined by the residence appraisal process) of the employee’s home.

PART 302–14—HOME MARKETING INCENTIVE PAYMENTS

■ 92. The authority citation for part 302–14 continues to read as follows:

Authority: 5 U.S.C. 5756.

§ 302–14.103 [Amended]

■ 93. Amend § 302–14.103 by removing from paragraph (b) “his/her residence” and adding “the employee’s residence” in its place.

PART 302–15—ALLOWANCE FOR PROPERTY MANAGEMENT SERVICES

■ 94. The authority citation for part 302–15 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1975 Comp., p. 586.

§ 302–15.1 [Amended]

■ 95. Amend § 302–15.1 by removing “his/her residence” and adding “the employee’s residence” in its place.

§ 302–15.70 [Amended]

■ 96. Amend § 302–15.70 by—

■ a. Removing from paragraph (d) “his/her residence” and adding “the employee’s residence” in its place; and

■ b. Removing from paragraph (e) “his/her mind” and “his/her residence” and adding “their mind” and “their residence” in their places, respectively.

PART 302–16—ALLOWANCE FOR MISCELLANEOUS EXPENSES

■ 97. The authority citation for part 302–16 continues to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1975 Comp., p. 586.

§ 302–16.202 [Amended]

■ 98. Amend § 302–16.202 by removing from paragraph (f) “his/her immediate” and adding “the employee’s immediate” in its place.

§ 302–16.203 [Amended]

■ 99. Amend § 302–16.203 by removing from paragraph (g) “he/she or a member of his/her” and adding “the employee or a member of the employee’s” in its place.

PART 302–17—TAXES ON RELOCATION EXPENSES

■ 100. The authority citation for part 302–17 continues to read as follows:

Authority: 5 U.S.C. 5724b; 5 U.S.C. 5738; E.O. 11609, as amended, 3 CFR, 1971–1975 Comp., p. 586.

§ 302–17.44 [Amended]

■ 101. Amend § 302–17.44 by removing from the introductory text “credit on his/her” and adding “credit on their” in its place.

§ 302–17.102 [Amended]

■ 102. Amend § 302–17.102 by removing from paragraph (b) “his/her behalf” and adding “the employee’s behalf” in its place.

PART 303–70—AGENCY REQUIREMENTS FOR PAYMENT OF EXPENSES CONNECTED WITH THE DEATH OF CERTAIN EMPLOYEES AND FAMILY MEMBERS

■ 103. The authority citation for part 303–70 continues to read as follows:

Authority: 5 U.S.C. 5721–5738; 5741–5742; E.O. 11609, 3 CFR, 1971–1975 Comp., p. 586; Presidential Memorandum dated September 12, 2011, “Delegation Under Section 2(a) of the Special Agent Samuel Hicks Families of Fallen Heroes Act.”

§ 303–70.1 [Amended]

■ 104. Amend § 303–70.1 by removing from paragraph (c) “his/her actual” and adding “the employee’s actual” in its place.

§ 303–70.301 [Amended]

■ 105. Amend § 303–70.301 by removing “his/her designated” and adding “their designated” in its place.

§ 303–70.400 [Amended]

■ 106. Amend § 303–70.400 by removing “his/her official” and adding “their official” in its place.

■ 107. Amend § 303–70.500 by revising the section heading to read as follows:

§ 303–70.500 When the employee, on a service agreement or a mandatory mobility agreement, dies at or while in transit to or from the employee’s official station OCONUS, must we return the employee’s immediate family, baggage, POV, and household goods to the former actual residence, new official station in CONUS, or alternate destination?

* * * * *

■ 108. Amend § 303–70.501 by revising the section heading to read as follows:

§ 303–70.501 Must we continue payment of relocation expenses for an employee's immediate family if the employee dies while in transit from an OCONUS official station to the employee's new official station within CONUS?

* * * * *

PART 304–2—DEFINITIONS

■ 109. The authority citation for part 304–2 continues to read as follows:

Authority: 5 U.S.C. 5707; 31 U.S.C. 1353.

§ 304–2.1 [Amended]

■ 110. Amend § 304–2.1 by removing from paragraph (1) of the definition “Meeting(s) or similar functions (meeting)” “his/her official” and adding “the employee's official” in its place.

PART 304–3—EMPLOYEE RESPONSIBILITY

■ 111. The authority citation for part 304–3 continues to read as follows:

Authority: 5 U.S.C. 5707; 31 U.S.C. 1353.

§ 304–3.2 [Amended]

■ 112. Amend § 304–3.2 by removing “his/her spouse” and adding “the employee's spouse” in its place.

PART 304–5—AGENCY RESPONSIBILITIES

■ 113. The authority citation for part 304–5 continues to read as follows:

Authority: 5 U.S.C. 5707; 31 U.S.C. 1353.

§ 304–5.3 [Amended]

■ 114. Amend § 304–5.3 by removing from paragraph (a) introductory text “he/she determines” and adding “the approving official determines” in its place.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 240208–0041]

RIN 0648–BM19

List of Fisheries for 2024

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is publishing its final List of Fisheries (LOF) for 2024, as required by the Marine Mammal Protection Act (MMPA). The LOF for 2024 reflects new information on interactions between commercial fisheries and marine mammals. NMFS must classify each commercial fishery on the LOF into one of three categories under the MMPA based on the level of mortality and serious injury of marine mammals that occurs incidental to each fishery. The classification of a fishery on the LOF determines whether participants in that fishery are subject to certain provisions of the MMPA, such as those on registration, observer coverage, and take reduction plan (TRP) requirements.

DATES: This rule is effective March 18, 2024.

ADDRESSES: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:

Jaclyn Taylor, Office of Protected Resources, 301–427–8402; Cheryl Cross, Greater Atlantic Region, 978–281–9100; Jessica Powell, Southeast Region, 727–824–5312; Dan Lawson, West Coast Region, 206–526–4740; Suzie Teerlink, Alaska Region, 907–586–7240; Elena Duke, Pacific Islands Region, 808–725–5085. Individuals who use a telecommunications device for the hearing impaired may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

What is the List of Fisheries?

Section 118 of the MMPA requires NMFS to place all U.S. commercial fisheries into one of three categories based on the level of incidental mortality and serious injury of marine mammals occurring in each fishery (16 U.S.C. 1387(c)(1)). The classification of a fishery on the LOF determines whether participants in that fishery may be required to comply with certain provisions of the MMPA, such as those on registration, observer coverage, and take reduction plan requirements. NMFS must reexamine the LOF annually, considering new information in the Marine Mammal Stock Assessment Reports (SARs) and other relevant sources, and publish in the **Federal Register** any necessary changes to the LOF after notice and opportunity for public comment (16 U.S.C. 1387 (c)(1)(C)).

How does NMFS determine in which category a fishery is placed?

The definitions for the fishery classification criteria can be found in the implementing regulations for section 118 of the MMPA (50 CFR 229.2). The criteria are also summarized here.

Fishery Classification Criteria

The fishery classification criteria consist of a two-tiered, stock-specific approach that first addresses the total impact of all fisheries on each marine mammal stock and then addresses the impact of individual fisheries on each stock. This approach is based on consideration of the rate, in numbers of animals per year, of incidental mortalities and serious injuries of marine mammals due to commercial fishing operations relative to the potential biological removal (PBR) level for each marine mammal stock. The MMPA (16 U.S.C. 1362 (20)) defines the PBR level as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock, while allowing that stock to reach or maintain its optimum sustainable population. This definition can also be found in the implementing regulations for section 118 of the MMPA (50 CFR 229.2).

Tier 1: Tier 1 considers the cumulative fishery mortality and serious injury for a particular stock. If the total annual mortality and serious injury of a marine mammal stock across all fisheries is less than or equal to 10 percent of the PBR level of the stock, all fisheries interacting with the stock will be placed in Category III (unless those fisheries interact with other stock(s) for which total annual mortality and serious injury is greater than 10 percent of PBR). Otherwise, these fisheries are subject to the next tier of analysis (Tier 2) to determine their classification.

Tier 2: Tier 2 considers fishery-specific mortality and serious injury for a particular stock.

Category I: Annual mortality and serious injury of a stock in a given fishery is greater than or equal to 50 percent of the PBR level (*i.e.*, frequent incidental mortality and serious injury of marine mammals).

Category II: Annual mortality and serious injury of a stock in a given fishery is greater than 1 percent and less than 50 percent of the PBR level (*i.e.*, occasional incidental mortality and serious injury of marine mammals).

Category III: Annual mortality and serious injury of a stock in a given fishery is less than or equal to 1 percent of the PBR level (*i.e.*, a remote likelihood of or no known incidental

mortality and serious injury of marine mammals).

Additional details regarding how the categories were determined are provided in the preamble to the final rule implementing section 118 of the MMPA (60 FR 45086, August 30, 1995).

Because fisheries are classified on a per-stock basis, a fishery may qualify as one category for one marine mammal stock and another category for a different marine mammal stock. A fishery is typically classified on the LOF at its highest level of classification (e.g., a fishery qualifying for Category III for one marine mammal stock and for Category II for another marine mammal stock will be listed under Category II). Stocks driving a fishery's classification are denoted with a superscript "1" in tables 1 and 2.

Other Criteria That May Be Considered

The tier analysis requires a minimum amount of data, and NMFS does not have sufficient data to perform a tier analysis on certain fisheries. Therefore, NMFS has classified certain fisheries by analogy to other fisheries that use similar fishing techniques or gear that are known to cause mortality or serious injury of marine mammals, or according to factors discussed in the final LOF for 1996 (60 FR 67063, December 28, 1995) and listed in the regulatory definition of a Category II fishery. In the absence of reliable information indicating the frequency of incidental mortality and serious injury of marine mammals by a commercial fishery, NMFS will determine whether the incidental mortality or serious injury is "occasional" by evaluating other factors such as fishing techniques, gear used, methods used to deter marine mammals, target species, seasons and areas fished, qualitative data from logbooks or fishermen reports, stranding data, and the species and distribution of marine mammals in the area, or at the discretion of the Assistant Administrator for Fisheries (50 CFR 229.2).

Further, eligible commercial fisheries not specifically identified on the LOF are deemed to be Category II fisheries until the next LOF is published (50 CFR 229.2).

How does NMFS determine which species or stocks are included as incidentally killed or injured in a fishery?

The LOF includes a list of marine mammal species and/or stocks incidentally killed or injured in each commercial fishery. The list of species and/or stocks incidentally killed or injured includes "serious" and "non-

serious" documented injuries as described later in the *List of Species and/or Stocks Incidentally Killed or Injured in the Pacific Ocean* and *List of Species and/or Stocks Incidentally Killed or Injured in the Atlantic Ocean, Gulf of Mexico, and Caribbean* sections. To determine which species or stocks are included as incidentally killed or injured in a fishery, NMFS annually reviews the information presented in the current SARs and injury determination reports. SARs are brief reports summarizing the status of each stock of marine mammals occurring in waters under U.S. jurisdiction. Information includes the identity and geographic range of the stock, population statistics related to abundance, trend, and annual productivity, notable habitat concerns, and estimates of human-caused mortality and serious injury (M/SI) by source. The SARs are based upon the best available scientific information and provide the most current and inclusive information on each stock's PBR level and level of interaction with commercial fishing operations. The best available scientific information used in the SARs and reviewed for the 2024 LOF generally summarizes data from 2016–2020. NMFS also reviews other sources of new information, including injury determination reports, bycatch estimation reports, observer data, logbook data, stranding data, disentanglement network data, fishermen self-reports (i.e., MMPA mortality/injury reports), and anecdotal reports from that time period. In some cases, more recent information may be available and used in the LOF.

For fisheries with observer coverage, species or stocks are generally removed from the list of marine mammal species and/or stocks incidentally killed or injured if no interactions are documented in the 5-year timeframe summarized in that year's LOF. For fisheries with no observer coverage and for observed fisheries with evidence indicating that undocumented interactions may be occurring (e.g., fishery has low observer coverage and stranding network data include evidence of fisheries interactions that cannot be attributed to a specific fishery), species and stocks may be retained for longer than 5 years. For these fisheries, NMFS will review the other sources of information listed above and use its discretion to decide when it is appropriate to remove a species or stock.

Where does NMFS obtain information on the level of observer coverage in a fishery on the LOF?

The best available information on the level of observer coverage and the spatial and temporal distribution of observed marine mammal interactions is presented in the SARs. Data obtained from the observer program and observer coverage levels are important tools in estimating the level of marine mammal mortality and serious injury in commercial fishing operations. Starting with the 2005 SARs, each Pacific and Alaska SAR includes an appendix with detailed descriptions of each Category I and II fishery on the LOF, including the observer coverage in those fisheries. For Atlantic fisheries, this information can be found in the LOF Fishery Fact Sheets. The SARs do not provide detailed information on observer coverage in Category III fisheries, because under the MMPA, Category III fisheries are not required to accommodate observers aboard vessels due to the remote likelihood of mortality and serious injury of marine mammals. Fishery information presented in the SARs' appendices and other resources referenced during the tier analysis may include: (1) the level of observer coverage; (2) the target species; (3) the levels of fishing effort; spatial and temporal distribution of fishing effort; (4) the characteristics of fishing gear and operations; (5) management and regulations; and (6) interactions with marine mammals. Copies of the SARs are available on the NMFS Office of Protected Resources website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region>. Information on observer coverage levels in Category I, II, and III fisheries can be found in the fishery fact sheets on the NMFS Office of Protected Resources' website: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/list-fisheries-summary-tables>. Additional information on observer programs in commercial fisheries can be found on the NMFS National Observer Program's website: <https://www.fisheries.noaa.gov/national/fisheries-observers/national-observer-program>.

How do I find out if a specific fishery is in Category I, II, or III?

The LOF includes three tables that list all U.S. commercial fisheries by Category. Table 1 lists all of the commercial fisheries in the Pacific Ocean (including Alaska), table 2 lists all of the commercial fisheries in the

Atlantic Ocean, Gulf of Mexico, and Caribbean, and table 3 lists all U.S. authorized commercial fisheries on the high seas. A fourth table, table 4, lists all commercial fisheries managed under applicable TRPs or take reduction teams (TRT).

Are high seas fisheries included on the LOF?

Beginning with the 2009 LOF, NMFS includes high seas fisheries in table 3 of the LOF, along with the number of valid High Seas Fishing Compliance Act (HSFCA) permits in each fishery. As of 2004, NMFS issues HSFCA permits only for high seas fisheries analyzed in accordance with the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). The authorized high seas fisheries are broad in scope and encompass multiple specific fisheries identified by gear type. For the purposes of the LOF, the high seas fisheries are subdivided based on gear type (e.g., trawl, longline, purse seine, gillnet, troll, etc.) to provide more detail on composition of effort within these fisheries. Many fisheries operate in both U.S. waters and on the high seas, creating some overlap between the fisheries listed in tables 1 and 2 and those in table 3. In these cases, the high seas component of the fishery is not considered a separate fishery, but an extension of a fishery operating within U.S. waters (listed in table 1 or 2). NMFS designates those fisheries in tables 1, 2, and 3 with an asterisk (*) after the fishery's name. The number of HSFCA permits listed in table 3 for the high seas components of these fisheries operating in U.S. waters does not necessarily represent additional effort not accounted for in tables 1 and 2. Many vessels/participants holding HSFCA permits also fish within U.S. waters and are included in the number of vessels and participants operating within those fisheries in tables 1 and 2.

HSFCA permits are valid for 5 years, during which time Fishery Management Plans (FMPs) can change. Therefore, some vessels/participants may possess valid HSFCA permits without the ability to fish under those permits because they were issued for a gear type that is no longer authorized under the most current FMP. For this reason, the number of HSFCA permits displayed in table 3 is likely higher than the actual U.S. fishing effort on the high seas. For more information on how NMFS classifies high seas fisheries on the LOF, see the preamble text in the final 2009 LOF (73 FR 73032, December 1, 2008). Additional information about HSFCA permits can be found at [https://](https://www.fisheries.noaa.gov/permit/high-seas-fishing-permits)

www.fisheries.noaa.gov/permit/high-seas-fishing-permits.

Where can I find specific information on fisheries listed on the LOF?

Starting with the 2010 LOF, NMFS developed summary documents, or fishery fact sheets, for each Category I and II fishery on the LOF. These fishery fact sheets provide the full history of each Category I and II fishery, including: (1) when the fishery was added to the LOF; (2) the basis for the fishery's initial classification; (3) classification changes to the fishery; (4) changes to the list of species and/or stocks incidentally killed or injured in the fishery; (5) fishery gear and methods used; (6) observer coverage levels; (7) fishery management and regulation; and (8) applicable TRPs or TRTs, if any. These fishery fact sheets are updated after each final LOF and can be found under "How Do I Find Out if a Specific Fishery is in Category I, II, or III?" on the NMFS Office of Protected Resources' website: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-protection-act-list-fisheries>, linked to the "List of Fisheries Summary" table. NMFS is developing similar fishery fact sheets for each Category III fishery on the LOF. However, due to the large number of Category III fisheries on the LOF and the lack of accessible and detailed information on many of these fisheries, the development of these fishery fact sheets is taking significant time to complete. NMFS began posting Category III fishery fact sheets online with the LOF for 2016.

Am I required to register under the MMPA?

Owners of vessels or gear engaging in a Category I or II fishery are required under the MMPA (16 U.S.C. 1387(c)(2)), as described in 50 CFR 229.4, to register with NMFS and obtain a marine mammal authorization to lawfully take marine mammals incidental to commercial fishing operations. The take of threatened or endangered marine mammals requires additional authorization. Owners of vessels or gear engaged in a Category III fishery are not required to register with NMFS or obtain a marine mammal authorization.

How do I register, renew, and receive my Marine Mammal Authorization Program (MMAP) authorization certificate?

NMFS has integrated the MMPA registration process, implemented through the MMAP, with existing state and Federal fishery license, registration, or permit systems for Category I and II

fisheries on the LOF. Participants in these fisheries are automatically registered under the MMAP and are not required to submit registration or renewal materials.

In the Pacific Islands, West Coast, and Alaska regions, NMFS will issue vessel or gear owners an authorization certificate via U.S. mail or with their state or Federal license or permit at the time of issuance or renewal. In the Southeast Region, NMFS will issue vessel or gear owners an authorization certificate via U.S. mail automatically at the beginning of each calendar year. In the Greater Atlantic Region, NMFS will issue vessel or gear owners an authorization certificate electronically. The certificate can be downloaded and/or printed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-authorization-program#obtaining-a-marine-mammal-authorization-certificate>. Printed copies can be mailed upon request by contacting nmfs.gar.mmapcert@noaa.gov or 978-281-9120.

Vessel or gear owners who participate in fisheries in these regions and have not received authorization certificates by the beginning of the calendar year, or with renewed fishing licenses, must contact the appropriate NMFS Regional Office (see **FOR FURTHER INFORMATION CONTACT**). Authorization certificates may also be obtained by visiting the MMAP website <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-authorization-program#obtaining-a-marine-mammal-authorization-certificate>.

The authorization certificate, or a copy (physical or electronic), must be on board the vessel while it is operating in a Category I or II fishery, or, for non-vessel fisheries, in the possession of the person in charge of the fishing operation (50 CFR 229.4(e)). Although efforts are made to limit the issuance of authorization certificates to only those vessel or gear owners that participate in Category I or II fisheries, not all state and Federal license or permit systems distinguish between fisheries as classified by the LOF. Therefore, some vessel or gear owners in Category III fisheries may receive authorization certificates even though they are not required for Category III fisheries.

Individuals fishing in Category I and II fisheries for which no state or Federal license or permit is required must register with NMFS by contacting their appropriate Regional Office (see **ADDRESSES**).

Am I required to submit reports when I kill or injure a marine mammal during the course of commercial fishing operations?

In accordance with the MMPA (16 U.S.C. 1387(e)) and 50 CFR 229.6, any vessel owner or operator, or gear owner or operator (in the case of non-vessel fisheries), participating in a fishery listed on the LOF, must report to NMFS all incidental mortalities and injuries of marine mammals that occur during commercial fishing operations, regardless of the category in which the fishery is placed (*i.e.*, Category I, Category II, or Category III) within 48 hours of the end of the fishing trip or, in the case of non-vessel fisheries, fishing activity. "Injury" is defined in 50 CFR 229.2 as a wound or other physical harm. In addition, any animal that ingests fishing gear or any animal that is released with fishing gear entangling, trailing, or perforating any part of the body is considered injured, regardless of the presence of any wound or other evidence of injury, and must be reported.

Mortality/injury reporting forms and instructions for submitting forms to NMFS can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-authorization-program#reporting-a-death-or-injury-of-a-marine-mammal-during-commercial-fishing-operations> or by contacting the appropriate regional office (see **FOR FURTHER INFORMATION CONTACT**). Forms may be submitted via any of the following means: (1) online using the electronic form; (2) emailed as an attachment to nmfs.mireport@noaa.gov; (3) faxed to the NMFS Office of Protected Resources at 301-713-0376; or (4) mailed to the NMFS Office of Protected Resources (mailing address is provided on the postage-paid form that can be printed from the web address listed above). Reporting requirements and procedures are found in 50 CFR 229.6.

Am I required to take an observer aboard my vessel?

Individuals participating in a Category I or II fishery are required to accommodate an observer aboard their vessel(s) upon request from NMFS. MMPA section 118 states that the Secretary is not required to place an observer on a vessel if the facilities for quartering an observer or performing observer functions are so inadequate or unsafe that the health or safety of the observer or the safe operation of the vessel would be jeopardized; thereby authorizing the exemption of vessels too

small to safely accommodate an observer from this requirement. Observer requirements are found in 50 CFR 229.7.

Am I required to comply with any marine mammal TRP regulations?

Table 4 provides a list of fisheries affected by TRPs and TRTs. TRP regulations are found at 50 CFR 229.30 through 229.37. A description of each TRT and copies of each TRP can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-take-reduction-plans-and-teams>. It is the responsibility of fishery participants to comply with applicable take reduction regulations.

Where can I find more information about the LOF and the MMAP?

Information regarding the LOF and the MMAP, including registration procedures and forms, current and past LOFs, descriptions of each Category I and II fishery and some Category III fisheries, observer requirements, and marine mammal mortality/injury reporting forms and submittal procedures may be obtained at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-protection-act-list-fisheries>, or from any NMFS Regional Office at the addresses listed below:

NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930-2298, Attn: Cheryl Cross;

NMFS, Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701, Attn: Jessica Powell;

NMFS, West Coast Region, Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213, Attn: Dan Lawson;

NMFS, Alaska Region, Protected Resources, P.O. Box 22668, 709 West 9th Street, Juneau, AK 99802, Attn: Suzie Teerlink; or

NMFS, Pacific Islands Regional Office, Protected Resources Division, 1845 Wasp Blvd., Building 176, Honolulu, HI 96818, Attn: Elena Duke.

Sources of Information Reviewed for the 2024 LOF

NMFS reviewed the marine mammal incidental mortality and serious injury information presented in the SARs for all fisheries to determine whether changes in fishery classification were warranted. The SARs are based on the best scientific information available at the time of preparation, including the level of mortality and serious injury of marine mammals that occurs incidental to commercial fishery operations and

the PBR levels of marine mammal stocks. The information contained in the SARs is reviewed by regional Scientific Review Groups (SRGs) representing Alaska, the Pacific (including Hawaii), and the U.S. Atlantic, Gulf of Mexico, and Caribbean. The SRGs were established by the MMPA to review the science that informs the SARs and to advise NMFS on marine mammal population status, trends, and stock structure, as well as on uncertainties in the science, research needs, and other issues.

NMFS also reviewed other sources of new information, including marine mammal stranding and entanglement data, observer program data, fishermen self-reports, reports to the SRGs, conference papers, FMPs, and ESA documents.

The LOF for 2024 was based on, among other things: (1) stranding data; (2) fishermen self-reports; and (3) SARs (primarily the 2022 SARs, which are based on data from 2016–2020). The SARs referenced in this LOF include: 2021 (87 FR 47385, August 3, 2022) and 2022 (88 FR 54592, August 11, 2023). The SARs are available at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region>.

Comments and Responses

NMFS received 28 comment letters on the proposed LOF for 2024 (88 FR 62748, September 13, 2023). Comments were received from 11 members of the public: (1) Alaska Department of Fish and Game (ADF&G); (2) California Coast Crab Association (CCCA); (3) Don't Cage Our Oceans; (4) Florida Department of Agriculture and Consumer Services; (5) Hawaii Division of Aquatic Resources (HI DAR); (6) Hawaii Longline Association (HLA); (7) Maine Department of Marine Resources (ME DMR); (8) Maine Lobstermen's Association (MLA); (9) Southeast Alaska Fishermen's Alliance (SEAFA) Taylor Shellfish Company; (10) United Southeast Alaska Gillnetters (USAG); and (11) U.S. Fish and Wildlife Service (FWS). NMFS additionally received a joint letter from American Cetacean Society-Oregon Chapter (ACS), Center for Biological Diversity, Defenders of Wildlife, EarthJustice, Endangered Habitats League, the Natural Resources Defense Council, Oceana, Ocean Defenders Alliance, and the Resource Renewal Institute (ACS *et al.*). Nine of the comment letters received were in response to NMFS request for public input on aquaculture fishery descriptions. NMFS thanks these commenters for providing information

in response to our aquaculture request, and we will consider all the aquaculture information submitted in future LOFs. Responses to substantive comments are below. Comments on actions not related to the LOF are not included.

Comments on Commercial Fisheries in the Pacific Ocean

Comment 1: ADF&G, SEAFA, USAG, and two members of the public opposed the reclassification of the AK Southeast salmon drift gillnet fishery from a Category II to a Category I fishery. ADF&G, SEAFA, USAG reiterated comments provided on the draft 2022 Southeast Alaska harbor porpoise SARs (8 FR 4162, January 24, 2023). Commenters raised concerns that the AK Southeast salmon drift gillnet fishery reclassification is based on inadequate harbor porpoise M/SI estimates and biased population size estimates in the 2022 SAR. Several commenters requested NMFS work with ADF&G to gather additional data on the harbor porpoise population, stock structure, and fisheries bycatch.

Response: NMFS appreciates the concerns raised in the comments. Comments on the 2022 SARs were addressed in the **Federal Register** notice for the final SARs (88 FR 54592, August 11, 2023). NMFS uses the best available scientific information to prepare the annual LOF, which includes reliance on the SARs for M/SI data. The LOF is re-evaluated annually to allow for the addition of best available information as it becomes available. NMFS continues to pursue options for future observer data to inform M/SI estimates for this fishery, and NMFS will consider data in future SARs to inform the annual LOF. Therefore, NMFS does not retain the AK Southeast salmon drift gillnet fishery as a Category II fishery and reclassifies the AK Southeast salmon drift gillnet fishery from a Category II to a Category I fishery.

Comment 2: ADF&G commented that the proposed reclassification of the AK Southeast salmon drift gillnet fishery from a Category II to a Category I fishery may result in changes to the fishery with potential economic impacts for the industry and consumers.

Response: The requirements for Category I and II fisheries under MMPA section 118(c) are the same. The MMPA section 118(c) requirements for Category I and II fisheries are to: (1) register with NMFS through the Marine Mammal Authorization Program; (2) accommodate observers aboard vessels, upon request; and (3) comply with any applicable take reduction plans. In addition, any vessel owner or operator participating in a fishery listed on the

LOF must report to NMFS all incidental mortalities and injuries of marine mammals that occur during commercial fishing operations, regardless of the category in which the fishery is placed (*i.e.*, Category I, Category II, or Category III). If NMFS takes a management action (*e.g.*, through the development of a TRP), then economic analyses of the effects of that TRP would be evaluated in subsequent rulemaking actions.

Comment 3: A member of the public recommends NMFS retain the superscript “1” for Eastern North Pacific Alaska resident stock of killer whale to indicate the stock is driving the Category II classification of the AK Bering Sea, Aleutian Islands flatfish trawl fishery based on the nine killer whale mortalities in the fishery in 2023. The commenter notes that NMFS has not yet released genetic information for the killer whale mortalities, but based on previous M/SI data for the AK Bering Sea, Aleutian Islands flatfish trawl fishery it is likely the whale mortalities in 2023 are from the Eastern North Pacific Alaska resident stock.

Response: NMFS agrees and retains the superscript “1” for the Eastern North Pacific Alaska resident stock of killer whale in the Category II AK Bering Sea, Aleutian Islands flatfish trawl fishery. While the Eastern North Pacific Alaska resident stock of killer whale stock is currently not driving the Category II classification of the AK Bering Sea, Aleutian Islands flatfish trawl fishery, there are past M/SI and more recent data that suggest that the M/SI is ongoing. NMFS will re-evaluate this in the next LOF cycle and adjust at that time, if necessary.

Comment 4: FWS recommends NMFS revise the Northern sea otter stock name on the list of species/stocks incidentally killed or injured for consistency with the current stock name in the SARs. They recommend revising Northern sea otter, South central AK to Northern sea otter, Southcentral AK.

Response: NMFS agrees and revises the stock name from Northern sea otter, South central AK to Northern sea otter, Southcentral AK on the list of species/stocks incidentally killed or injured in the following fisheries: (1) Category II AK Cook Inlet salmon set gillnet, (2) Category II AK Prince William Sound salmon drift gillnet and (3) Category III AK Prince William Sound salmon set gillnet.

Comment 5: HI DAR requests NMFS revisit the classification of the Category II HI shortline fishery. The Category II HI shortline fishery was classified by analogy to the HI longline fishery in the 2010 LOF. HI DAR states that there are differences in gear composition between

the HI shortline fishery and HI longline fishery that present marked differences in potential threats to marine mammals. DAR notes that shortline gear is used by the HI seamount fishery, also known as the HI offshore handline fishery, which consists of fewer than 10 vessels and not all vessels currently use the gear. HI DAR requests NMFS review new information on shortline gear including its risk to marine mammals.

Response: The HI shortline fishery is classified as Category II by analogy to the HI longline fishery based on similarities between the gears used in the fisheries. NMFS may classify fisheries by analogy to other fisheries that use similar fishing techniques or gear that are known to cause M/SI of marine mammals, or according to factors discussed in the final LOF for 1996 (60 FR 67063, December 28, 1995) and listed in the regulatory definition of a Category II fishery. The HI shortline fishery lacks a dedicated observer program or an electronic monitoring component to assess the level of M/SI, or lack thereof, within the fishery. While multiple gear types are used within the HI shortline fishery, vessels may deploy shortline gear, which sets hooks in a manner consistent with longline vessels. Additionally, the fishery operates in locations that overlap with Main Hawaiian Island (MHI) insular false killer whale's range and has the potential for interactions with these animals. In addition, HI DAR did not provide specific information on differences between HI shortline and longline gear. Therefore, NMFS is not making changes to the HI shortline fishery for the 2024 LOF.

Comment 6: HLA supports removing the Hawaii stock of striped dolphin from the list of species/stocks incidentally killed or injured in the Category I HI deep-set longline fishery. They also support removing the Hawaii stock of fin whale and Central North Pacific stock of humpback whale from the list of species/stocks incidentally killed or injured in the Category II HI shallow-set longline fishery.

Response: NMFS agrees and removes the stocks from the list of species/stocks incidentally killed or injured in the respective fisheries.

Comment 7: HLA reiterates a previous comment recommending NMFS remove the MHI insular and Northwestern Hawaiian Islands (NWHI) stocks of false killer whales from the list of species and/or stocks incidentally killed or injured in the Category I HI deep-set longline fishery. The HI deep-set longline fishery is observed with 20 percent coverage, and there have been no documented M/SI of the MHI insular

false killer whale stock in the most recent 5-year period. HLA notes that (a) the False Killer Whale Take Reduction Plan (FKWTRP) closed the deep-set longline fishery for almost the entire range of the MHI insular stock, (b) since this change was made in 2013 there have been no false killer whale interactions in the fishery, and (c) there has never been a deep-set longline fishery M/SI in the very small area of the stocks' range where the fishery operates. They also state that no information has been presented to the False Killer Whale Take Reduction Team or the Pacific Scientific Review Group suggesting any false killer whale M/SI in the deep-set fishery can reliably be attributed to the MHI insular or NWHI stocks of false killer whales. HLA requests that NMFS remove the MHI insular and NWHI stocks of false killer whales from the list of species and/or stocks incidentally killed or injured in the Category I HI deep-set longline fishery.

Response: This comment has been addressed previously (see 84 FR 22051, May 16, 2019; 85 FR 21079, April 16, 2020; 86 FR 3028, January 14, 2021; 88 FR 16899, March 21, 2023). The MHI insular stock of false killer whales have been documented via telemetry to move far enough offshore to reach longline fishing areas (Bradford *et al.*, 2015). The MHI insular, Hawaii pelagic, and NWHI stocks have partially overlapping ranges. MHI insular false killer whales have been satellite tracked as far as 115 kilometers (km) from the MHI, while pelagic stock animals have been tracked to within 11 km of the MHI and throughout the NWHI. Thus, M/SI of false killer whales of unknown stock within the stock overlap zones must be prorated to MHI insular, pelagic, or NWHI stocks.

Annual bycatch estimates are prorated using a process outlined in detail in the SARs, which account for M/SI that occur within the MHI-pelagic or NWHI-pelagic overlap zones. As described in the 2021 SAR (Carretta *et al.*, 2022), from 2015–2019 the mean estimated annual M/SI of false killer whales was 9.8. This results in a prorated mean estimated annual M/SI of 0.03 for the MHI insular stock and 0.1 for the NWHI stock.

MHI insular false killer whales have been documented with injuries consistent with fisheries interactions that have not been attributed to a specific fishery (Baird *et al.*, 2014). For observed fisheries with evidence indicating that undocumented interactions may be occurring (*e.g.*, fishery has evidence of fisheries interactions that cannot be attributed to

a specific fishery, and stranding network data include evidence of fisheries interactions that cannot be attributed to a specific fishery), stocks may be retained on the LOF for longer than 5 years. For these fisheries, NMFS will review the other sources of relevant information to determine when it is appropriate to remove a species or stock from the LOF. Therefore, NMFS retains both the MHI insular and NWHI false killer whale stocks on the list of species and/or stocks incidentally killed or injured in the Category I HI deep-set longline fishery.

Comment 8: ACS *et al.* supports NMFS reclassifying the CA Dungeness crab pot fishery from a Category II to a Category I fishery based on incidental M/SI of the Central America/Southern Mexico-CA/OR/WA stock of humpback whale. They also state that Rmax (maximum net productivity rate) for the Central America/Southern Mexico-CA/OR/WA stock of humpback whale used in the 2022 SAR is inconsistent with the Guidelines for Preparing Stock Assessment Reports Pursuant to the 1994 Amendments to the Marine Mammal Protection Act.

Response: NMFS thanks the organizations for their comment and reclassifies the CA Dungeness crab pot fishery from a Category II to a Category I fishery. Comments on the draft 2022 SARs, including selection of parameters such as Rmax, were addressed in the **Federal Register** notice for the final SARs (88 FR 54592, August 11, 2023).

Comment 9: CCCA opposes NMFS reclassifying the CA Dungeness crab pot fishery from a Category II to a Category I fishery based on incidental M/SI of the Central America/Southern Mexico-CA/OR/WA stock of humpback whale. They state that the reclassification is not based on the best available information since it uses M/SI data from 2016–2020. CCCA notes that in 2016, there was an unprecedented 22 humpback whale entanglements and that this increase was attributed to anomalous ocean conditions that changed the whales' migratory path. Since 2016, CA Department of Fish and Wildlife has implemented regulations to reduce entanglement risk. CCCA state that in 2021 there was one humpback whale entanglement and four in 2022 in the CA Dungeness crab pot fishery. If the more recent M/SI data are used and excludes the 2016 data, the estimated annual M/SI is below 50 percent of PBR for the Central America/Southern Mexico-CA/OR/WA stock of humpback whale and therefore a Category II fishery.

Response: NMFS appreciates the comments about the implementation of

new regulations and measures to address entanglements in the CA Dungeness crab pot fishery following the increased entanglements in 2016. We also acknowledge the efforts of CA Department of Fish and Wildlife and other stakeholders in California to take proactive steps to reduce entanglement risks in the CA Dungeness crab pot fishery through convening the California Dungeness Crab Fishing Gear Working Group and subsequent development and implementation of the Risk Assessment and Mitigation Program. NMFS uses the best available scientific information to prepare the annual LOF, which includes relying on the SARs for M/SI data. The LOF for 2024 was based on, among other things: (1) stranding data; (2) fishermen self-reports; and (3) SARs (primarily the 2022 SARs) which are based on data from 2016–2020. As M/SI information becomes available from later years, NMFS will review classification of the CA Dungeness crab pot fishery in a future LOF. For the 2024 LOF, NMFS reclassifies the CA Dungeness crab pot fishery from a Category II to a Category I fishery.

Comment 10: ACS *et al.* requests NMFS add the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale to the list of species/stocks incidentally killed or injured in the Category III WA/OR/CA groundfish/finfish hook and line fishery based on an entanglement in 2021.

Response: The injury determination for the 2021 humpback whale entanglement in the Category III WA/OR/CA groundfish/finfish hook and line fishery (Carretta *et al.* 2023a) was finalized after the proposed 2024 LOF published. NMFS adds the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale to the list of species/stocks incidentally killed or injured in the Category III WA/OR/CA groundfish/finfish hook and line fishery. NMFS will conduct the tier analysis for this M/SI in the Category III WA/OR/CA groundfish/finfish hook and line fishery for the 2025 LOF.

Comment 11: ACS *et al.* recommends NMFS add the California experimental pot fishery targeting king and other deep water crab species to the LOF and classify the fishery by analogy as a Category II fishery. They note that the fishery uses large pot gear with vertical buoy lines in depths greater than 125 fathoms (228.6 m) off the coast of California north of Pigeon Point (south of San Francisco). ACS *et al.* states there was a humpback whale entanglement in this fishery in 2021 near the Channel Islands National Marine Sanctuary.

Response: Any eligible commercial fishery not specifically identified on the LOF is deemed to be a Category II fishery until the next LOF is published (50 CFR 229.2). NMFS will consider the comments provided by ACS *et al.* in a future proposed LOF.

Comment 12: ACS *et al.* requests NMFS add the California groundfish/finfish set net fishery as a Category II fishery. They note that the 2024 LOF does not include the California groundfish/finfish set net fishery, which is managed with other types of fixed gear in the open access sector under the Pacific Coast Groundfish Fishery Management Plan (Groundfish FMP).

Response: NMFS acknowledges that the use of gillnets remains an authorized gear type in areas south of 38 degrees N. lat. (50 CFR 660.330(b) and 50 CFR 660.330(b)(2)(ii)) under the Groundfish FMP. However, NMFS' review of fishing effort information, including landings and observer data, indicate that there does not appear to be any dedicated or stand-alone use of gillnets for harvesting groundfish on the West Coast that is not already associated with other Category II gillnet fisheries on the LOF. Available information suggests that some limited landings of groundfish species may occur under the open access provisions of the Groundfish FMP while vessels are participating in the Category II CA halibut/white seabass and other species set gillnet (>3.5 inch (in) mesh) fishery in California. Therefore, gillnet fishing resulting in the harvest of species managed under the Groundfish FMP is already reflected on the LOF as Category II fishing effort.

Comments on Commercial Fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean

Comment 13: ME DMR and MLA reiterate previous comments requesting that the Maine state waters trap/pot fishery be separated out from the broader Category I Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot fishery and classified as a separate and independent Category II fishery. Both ME DMR and MLA cite the rarity of North Atlantic right whales in Maine state waters, lack of attributed right whale entanglements in the Maine lobster fishery, the implementation of unique gear marking and additional risk reduction measures combined with an increase in North Atlantic right whale monitoring in the Gulf of Maine as the justification that the ME state waters lobster trap pot fishery is a separate and distinct fishery.

ME DMR and MLA note that state regulations require that all buoy lines in state waters and "the sliver" have a

1700-pound (lb) (771 kg) weak insertion 50 percent of the way down the vertical line, or approved 1700-lb (771 kg) breaking strength line in the top 50 percent of the vertical line. Both commenters assert that the Maine state fishery has unique gear markings that distinguishes it from rest of the Category I Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot fishery. In Maine state waters, fishermen must have a 36-inch (91.4 cm) purple mark in the top two fathoms of their line, another 12 inch (30.5 cm) mark midway down the line, and another 12 inch (30.5 cm) mark at the bottom of the line. Federal green marks are not allowed in Maine state waters.

ME DMR and MLA state that North Atlantic right whale monitoring efforts have increased substantially in the Gulf of Maine. Since September 2022, New England Aquarium has been conducting aerial surveys off the coast of Maine and to date, 12 surveys have been completed with no right whale sightings. In addition, Woods Hole Oceanographic Institute is conducting acoustic glider work in the Gulf of Maine. Data from December 2022–April 2023 and June–August 2023 had no confirmed detections of right whales and the former timeframe had only a few possible detections.

Both commenters acknowledge that Maine and Massachusetts have taken different approaches to risk reduction in their respective fisheries. They stress that Massachusetts state waters have concentrated aggregations of right whales resulting in entanglement risks during specific seasons. In contrast, right whale sightings in Maine state waters are infrequent, resulting in a low, diffuse entanglement risk coast wide during most of the year. Based on the predictable seasonal aggregations of right whales in Cape Cod Bay, Massachusetts used a seasonal closure as their primary risk reduction measure. While Maine, with diffuse risk, used "trawling up" as the primary risk reduction measure. Based on this, NMFS should not compare the two states' differing approaches as a basis for decision making to reclassify the Maine state lobster trap/pot fishery as a separate and distinct fishery from the broader Category I Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot fishery.

Response: NMFS recognizes that the state of Maine has modified their lobster trap/pot fishery in alignment with the Atlantic Large Whale Take Reduction Plan requirements that were finalized in 2021 (86 FR 5990, September 17, 2021), has expanded acoustic monitoring, and has recently commenced visual surveys.

However, cumulatively, these efforts do not differentiate the Maine state lobster fishery as a distinct fishery. To reiterate the responses stated in previous LOFs (88 FR 16899, March 21, 2023 and 87 FR 23122, April 19, 2022), the state of Massachusetts was considered to be a unique, separate fishery because of the combination of measures that have been taken (see previous LOF: 88 FR 16899, March 21, 2023). As stated in our previous response, in making our decision, we considered the changes that the state of Massachusetts made (including gear changes that distinguish Massachusetts rope from other states, due to increased weak rope and insert requirements and increased marking frequency, amplified closures and a long time series of dedicated continual monitoring efforts) collectively, not as individual, standalone factors.

With recent changes to gear markings, we are only now beginning to definitively trace entanglement gear to its source. According to data spanning 2020–2022, entanglements with exclusively purple gear markings, signifying gear fished in Maine state waters, include three minke and two humpback whales. However, for the majority of documented entanglement cases spanning 2020–2022, gear could not be attributed to a specific origin (for 92 percent of North Atlantic right whale, 85 percent of humpback whale, 71 percent of minke whale, and 100 percent of fin whale cases).

The state of Maine's growing monitoring effort may inform future decisions regarding how to reduce North Atlantic right whale M/SI, as well as M/SI of other endangered large whales and marine mammals. As we continue to gather more data on whale distribution, habitat use, movement and M/SI due to entanglements, NMFS will evaluate whether splitting out the Maine state waters trap/pot fishery from the broader Category I Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot fishery is appropriate.

Summary of Changes From the Proposed Rule

In this final rule, NMFS corrects an error from the proposed rule in table 2 and removes the Category III U.S. Atlantic tuna purse seine fishery. On October 3, 2022, NMFS published a final rule that discontinued the use of purse seines in the Atlantic highly migratory species bluefin tuna fishery (87 FR 59966, effective January 1, 2023).

Based on public comment, and for consistency with the current stock name in the SARs, NMFS revises the stock name from Northern sea otter, South central AK to Northern sea otter,

Southcentral AK on the list of species/stocks incidentally killed or injured in the following fisheries: (1) Category II AK Cook Inlet salmon set gillnet, (2) Category II AK Prince William Sound salmon drift gillnet, and (3) Category III AK Prince William Sound salmon set gillnet.

Based on public comment, NMFS retains the “1” superscript for the Eastern North Pacific Alaska resident stock of killer whale in the Category II AK Bering Sea, Aleutian Islands flatfish trawl fishery.

Based on public comment, NMFS adds the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale to the list of species/stocks incidentally killed or injured in the Category III WA/OR/CA groundfish/finfish hook and line fishery.

Summary of Changes to the LOF for 2024

The following summarizes changes to the LOF for 2024, including the classification of fisheries, fisheries listed, the estimated number of vessels/persons in a particular fishery, and the species and/or stocks that are incidentally killed or injured in a particular fishery. NMFS adds one fishery, removes seven fisheries, and reclassifies four fisheries in the LOF for 2024. NMFS also makes changes to the estimated number of vessels/persons and list of species and/or stocks killed or injured in certain fisheries. The classifications and definitions of U.S. commercial fisheries for 2024 are identical to those provided in the LOF for 2023, except for the changes discussed below. State and regional abbreviations used in the following paragraphs include AK (Alaska), CA (California), FL (Florida), GA (Georgia), HI (Hawaii), NC (North Carolina), OR (Oregon), SC (South Carolina), WA (Washington), and WNA (Western North Atlantic).

Commercial Fisheries in the Pacific Ocean

Classification of Fisheries

NMFS reclassifies the Category II AK Southeast salmon drift gillnet fishery to a Category I fishery.

NMFS reclassifies the Category II CA Dungeness crab pot fishery to a Category I fishery.

NMFS reclassifies the Category II AK Bering Sea, Aleutian Islands Pacific cod pot fishery to a Category III fishery.

Fishery Name and Organizational Changes and Clarification

NMFS combines the Category III AK Dungeness crab fishery with the

Category III AK miscellaneous invertebrates handpick fishery.

NMFS removes the Category III AK roe herring and food/bait herring beach seine fishery from the LOF.

NMFS removes the Category III AK state-managed waters of Prince William Sound groundfish trawl fishery.

NMFS removes the Category III AK Bering Sea, Aleutian Islands groundfish hand troll and dinglebar troll fishery from the LOF.

NMFS removes the Category III AK herring spawn on kelp dive hand/mechanical collection fishery from the LOF.

NMFS adds the superscript “1” to the southern Southeast Alaska inland waters stocks of harbor porpoise to indicate the stock is driving the Category I classification of the AK Southeast salmon drift gillnet fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/OR/WA stocks of humpback whale to indicate the stock is driving the Category I classification of the CA Dungeness crab pot fishery. NMFS also removes the superscript “1” from Eastern North Pacific stock of blue whale to indicate the stock is not driving the Category I classification of the CA Dungeness crab pot fishery.

NMFS removes the superscript “1” from the CA/OR/WA stock of minke whale to indicate the stock is no longer driving the Category II classification of the CA thresher shark/swordfish drift gillnet (≥ 14 in mesh) fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico—CA/OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the CA halibut/white seabass and other species set gillnet (>3.5 in mesh) fishery.

NMFS adds the superscript “2” to the Category II AK Cook Inlet salmon set gillnet fishery to indicate this fishery is classified by analogy.

NMFS removes the superscript “2” from the Category II AK Yakutat salmon set gillnet fishery to indicate this fishery is not classified by analogy to other Category II gillnet fisheries. NMFS also adds the superscript “1” to the Yakutat/Southeast Alaska offshore waters stock of harbor porpoise to indicate the stock is driving the Category II classification of the AK Yakutat salmon set gillnet fishery.

NMFS removes the superscript “1” from the Western North Pacific stock of humpback whale to indicate the stocks is no longer driving the Category II classification of the AK Bering Sea, Aleutian Islands flatfish trawl fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/

OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the CA coonstripe shrimp pot fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the CA spiny lobster fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the CA spot prawn pot fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the OR Dungeness crab pot fishery.

NMFS adds the superscript “1” to both the Central America/Southern Mexico-CA/OR/WA and Mainland Mexico-CA/OR/WA stocks of humpback whale to indicate the stocks are driving the Category II classification of the WA/OR/CA sablefish pot fishery.

NMFS adds the superscript “1” to the Central America/Southern Mexico-CA/OR/WA stock of humpback whale to indicate the stock is driving the Category II classification of the WA coastal Dungeness crab pot fishery.

NMFS adds the superscript “1” to the North Pacific stock of sperm whale to indicate the stock is driving the Category II classification of the AK Gulf of Alaska sablefish longline fishery.

Number of Vessels/Persons

NMFS updates the estimated number of vessels/persons in the Pacific Ocean (table 1) as follows:

Category I

- HI deep-set longline fishery from 150 to 146 vessels/persons; and
- AK Southeast salmon drift gillnet fishery from 474 to 371 vessels/persons.

Category II

- AK Bristol Bay salmon drift gillnet fishery from 1,862 to 1,521 vessels/persons;
- AK Bristol Bay salmon set gillnet fishery from 979 to 855 vessels/persons;
- AK Kodiak salmon set gillnet fishery from 188 to 128 vessels/persons;
- AK Cook Inlet salmon set gillnet fishery from 736 to 479 vessels/persons;
- AK Cook Inlet salmon drift gillnet fishery from 569 to 355 vessels/persons;
- AK Peninsula/Aleutian Islands salmon drift gillnet fishery from 162 to 148 vessels/persons;
- AK Peninsula/Aleutian Islands salmon set gillnet fishery from 113 to 75 vessels/persons;

- AK Prince William Sound salmon drift gillnet fishery from 537 to 483 vessels/persons;
- AK Yakutat salmon set gillnet fishery from 168 to 95 vessels/persons;
- AK Bering Sea, Aleutian Islands flatfish trawl fishery from 32 to 29 vessels/persons;
- AK Bering Sea, Aleutian Islands pollock trawl fishery from 102 to 116 vessels/persons;
- AK Gulf of Alaska sablefish longline fishery from 295 to 177 vessels/persons;
- American Samoa longline fishery from 18 to 11 vessels/persons; and
- HI shortline fishery from 11 to 8 vessels/persons.

Category III

- AK Kuskokwim, Yukon, Norton Sound, Kotzebue salmon gillnet fishery from 1,778 to 360 vessels/persons;
- AK Prince William Sound salmon set gillnet fishery from 29 to 25 vessels/persons;
- AK roe herring and food/bait herring gillnet fishery from 920 to 15 vessels/persons;
- HI inshore gillnet fishery from 27 to 26 vessels/persons;
- AK Cook Inlet salmon purse seine fishery from 83 to 16 vessels/persons;
- AK Kodiak salmon purse seine fishery from 376 to 159 vessels/persons;
- AK Southeast salmon purse seine fishery from 315 to 206 vessels/persons;
- AK roe herring and food/bait herring purse seine fishery from 356 to 31 vessels/persons;
- AK salmon beach seine fishery from 31 to two vessels/persons;
- AK salmon purse seine (Prince William Sound, Chignik, Alaska Peninsula) fishery from 936 to 298 vessels/persons;
- HI throw net, cast net fishery from 16 to 13 vessels/persons;
- HI seine net fishery from 16 to 17 vessels/persons;
- AK Gulf of Alaska groundfish hand troll and dinglebar troll fishery from unknown to four vessels/persons;
- AK salmon troll fishery from 1,908 to 850 vessels/persons;
- American Samoa tuna troll fishery from three to six vessels/persons;
- HI troll fishery from 1,293 to 1,124 vessels/persons;
- HI rod and reel fishery from 246 to 235 vessels/persons;
- Guam tuna troll fishery from 465 to 450 vessels/persons;
- AK Bering Sea, Aleutian Islands Pacific cod longline fishery from 45 to 26 vessels/persons;
- AK Bering Sea, Aleutian Islands sablefish longline fishery from 22 to eight vessels/persons;

- AK Bering Sea, Aleutian Islands halibut longline fishery from 127 to 84 vessels/persons;
- AK Gulf of Alaska halibut longline fishery from 855 to 689 vessels/persons;
- AK Gulf of Alaska Pacific cod longline fishery from 92 to 23 vessels/persons;
- AK octopus/squid longline fishery from three to zero vessels/persons;
- HI kaka line fishery from 16 to 17 vessels/persons;
- HI vertical line fishery from five to six vessels/persons;
- AK Bering Sea, Aleutian Islands Atka mackerel trawl fishery from 13 to 17 vessels/persons;
- AK Bering Sea, Aleutian Islands Pacific cod trawl fishery from 72 to 64 vessels/persons;
- AK Bering Sea, Aleutian Islands rockfish trawl fishery from 17 to 22 vessels/persons;
- AK Gulf of Alaska flatfish trawl fishery from 36 to 16 vessels/persons;
- AK Gulf of Alaska Pacific cod trawl fishery from 55 to 12 vessels/persons;
- AK Gulf of Alaska pollock trawl fishery from 67 to 60 vessels/persons;
- AK Gulf of Alaska rockfish trawl fishery from 43 to 35 vessels/persons;
- AK Kodiak food/bait herring otter trawl fishery from four to zero vessels/persons;
- AK shrimp otter trawl and beam trawl fishery from 38 to 12 vessels/persons;
- AK Bering Sea, Aleutian Islands Pacific cod pot fishery from 59 to 80 vessels/persons;
- AK Bering Sea, Aleutian Islands sablefish pot fishery from 16 to 15 vessels/persons;
- AK Bering Sea, Aleutian Islands crab pot fishery from 540 to 73 vessels/persons;
- AK Gulf of Alaska crab pot fishery from 271 to 86 vessels/persons;
- AK Gulf of Alaska Pacific cod pot fishery from 116 to 48 vessels/persons;
- AK Gulf of Alaska sablefish pot fishery from 248 to 129 vessels/persons;
- AK Southeast Alaska shrimp pot fishery from 99 to 104 vessels/persons;
- AK shrimp pot, except Southeast fishery from 141 to 77 vessels/persons;
- AK octopus/squid pot fishery from 15 to zero vessels/persons;
- HI crab trap fishery from three to four vessels/persons;
- HI crab net fishery from three to four vessels/persons;
- HI Kona crab loop net fishery from 24 to 13 vessels/persons;
- American Samoa bottomfish fishery from 46 to 44 vessels/persons;
- Commonwealth of the Northern Mariana Islands bottomfish fishery from 12 to seven vessels/persons;

- Guam bottomfish fishery from 84 to 63 vessels/persons;
- HI bottomfish handline fishery from 404 to 382 vessels/persons;
- HI inshore handline fishery from 182 to 158 vessels/persons;
- HI pelagic handline fishery from 311 to 271 vessels/persons;
- AK Gulf of Alaska groundfish jig fishery from 214 to 68 vessels/persons;
- AK halibut jig fishery from 71 to five vessels/persons;
- AK herring spawn on kelp pound net fishery from 291 to 143 vessels/persons;
- AK Southeast herring roe/food/bait pound net fishery from two to one vessels/persons;
- AK clam fishery from 130 to 57 vessels/persons;
- AK miscellaneous invertebrates handpick fishery from 214 to 188 vessels/persons;
- HI black coral diving fishery from less than three to none recorded;
- HI handpick fishery from 28 to 25 vessels/persons;
- HI lobster diving fishery from 10 to 12 vessels/persons;
- HI spearfishing fishery from 79 to 67 vessels/persons; and
- HI aquarium collecting fishery from 39 to none recorded.

List of Species and/or Stocks Incidentally Killed or Injured in the Pacific Ocean

NMFS adds the Beringia stock of bearded seal to the list of species/stocks incidentally killed or injured in the Category II AK Bering Sea, Aleutian Islands pollock trawl fishery.

NMFS adds the U.S. stock of California sea lion to the list of species/stocks incidentally killed or injured in the Category III CA sea cucumber trawl fishery.

NMFS removes the Hawaii stock of striped dolphin from the list of species/stocks incidentally killed or injured in the Category I HI deep-set longline fishery.

NMFS removes the Hawaii stock of fin whale and Central North Pacific stock of humpback whale from the list of species/stocks incidentally killed or injured in the Category II HI shallow-set longline fishery.

NMFS revises marine mammal stock names on the list of species/stocks incidentally killed or injured for consistency with the current stock names in the SARs as follows:

Category II AK Bristol Bay Salmon Drift Gillnet Fishery

- Harbor seal, Bering Sea to harbor seal, Bristol Bay; and

Category II AK Gulf of Alaska Sablefish Longline

- Northern elephant seal, California to Northern elephant seal, California breeding.

NMFS updates the harbor porpoise stocks on the list of species/stocks incidentally killed or injured based on the revised stock structures in the 2022 SAR (Young *et al.*, 2023) as follows:

Category I AK Southeast Salmon Drift Gillnet Fishery

- Harbor porpoise, southeast Alaska to harbor porpoise, southern Southeast Alaska inland waters and harbor porpoise, northern Southeast Alaska inland waters, and

Category II AK Yakutat Salmon Set Gillnet Fishery

- Harbor porpoise, southeast Alaska to harbor porpoise, Yakutat/Southeast Alaska offshore waters.

NMFS updates the humpback whale stocks on the list of species/stocks incidentally killed or injured based on the revised stock structures in the 2022 SAR (Carretta *et al.*, 2023; Young *et al.*, 2023) as follows:

Category I AK Southeast Salmon Drift Gillnet Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II CA Thresher Shark/Swordfish Drift Gillnet (≥ 14 in Mesh) Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II CA Halibut/White Seabass and Other Species Set Gillnet (>3.5 in Mesh) Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II AK Kodiak Salmon Set Gillnet Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II AK Cook Inlet Salmon Set Gillnet Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II AK Prince William Sound Salmon Drift Gillnet Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II AK Yakutat Salmon Set Gillnet Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II AK Bering Sea, Aleutian Islands Pollock Trawl Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category II CA Coonstripe Shrimp Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II CA Spiny Lobster Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II CA Spot Prawn Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II CA Dungeness Crab Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II OR Dungeness Crab Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II WA/OR/CA Sablefish Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and humpback whale, Mainland Mexico-CA/OR/WA stock;

Category II WA Coastal Dungeness Crab Pot Fishery

- Humpback whale, CA/OR/WA to humpback whale, Central America/Southern Mexico-CA/OR/WA and

humpback whale, Mainland Mexico-CA/OR/WA stock;

Category III AK Cook Inlet Salmon Purse Seine Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III AK Kodiak Salmon Purse Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III AK Southeast Salmon Purse Seine Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III AK Bering Sea, Aleutian Islands Pacific Cod Pot Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III Southeast Alaska Crab Pot Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III Southeast Alaska Shrimp Pot Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific;

Category III HI Crab Trap Fishery

- Humpback whale, Central North Pacific to humpback whale, Hawai'i, and

Category III AK/WA/OR/CA Commercial Passenger Vessels Fishery; and,

- Humpback whale, Central North Pacific to humpback whale, Hawai'i and humpback whale, Mexico-North Pacific.

Commercial Fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean

Classification of Fisheries

NMFS reclassifies the Category III U.S. Mid-Atlantic mixed species stop seine/weir/pound net (except the NC roe mullet stop net) fishery to a Category II fishery. NMFS also adds the fishery to the list of affected fisheries for the Bottlenose Dolphin Take Reduction Plan in table 4.

Addition of Fisheries

NMFS adds the Virginia shrimp trawl fishery as a Category II fishery.

Fishery Name and Organizational Changes and Clarification

NMFS removes the superscript “1” from the WNA stock of long-finned pilot whale to indicate the stock is no longer driving the Category II classification of the Northeast mid-water trawl (including pair trawl) fishery.

NMFS combines the Category II Northeast anchored float gillnet fishery into the Category I Northeast sink gillnet fishery. This change does not affect either fisheries’ requirements under the Harbor Porpoise or Atlantic Large Whale TRPs (see table 4).

NMFS revises the fishery descriptions for the Category I Northeast/Mid-Atlantic American lobster trap/pot fishery and Category II Atlantic mixed species trap/pot fishery. NMFS adds Jonah crab as a target species for the Category I Northeast/Mid-Atlantic American lobster trap/pot fishery and removes Jonah crab as a target species from the Category II Atlantic mixed species trap/pot fishery. NMFS also revises the name of the Category I Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot fishery.

Number of Vessels/Persons

NMFS updates the estimated number of vessels/persons in the Atlantic Ocean, Gulf of Mexico, and Caribbean (table 2) as follows:

Category I

- Northeast sink gillnet fishery from 4,072 to 4,924 vessels/persons;

Category II

- NC inshore gillnet fishery from 2,676 to 1,157 vessels/persons; and,
- NC long haul seine fishery from 22 to 10 vessels/persons.

List of Species and/or Stocks Incidentally Killed or Injured in the Atlantic Ocean, Gulf of Mexico, and Caribbean

NMFS corrects an administrative error in table 2. NMFS updates the bottlenose dolphin stock name from FL Bay estuarine to FL Bay in the list of species/stocks incidentally killed or injured in the Category III FL spiny lobster trap/pot fishery.

NMFS adds the WNA stock of harp seal to the list of species/stocks incidentally killed or injured in the Category I mid-Atlantic gillnet fishery.

NMFS adds the WNA stock of white-sided dolphin to the list of species/stocks incidentally killed or injured in the Category II Northeast mid-water trawl (including pair trawl) fishery.

NMFS adds the Biscayne Bay estuarine stock of bottlenose dolphin to the list of species/stocks incidentally

killed or injured in the Category II Atlantic blue crab trap/pot fishery.

NMFS adds the Charleston estuarine system stock of bottlenose dolphin to the list of species/stocks incidentally killed or injured in the Category III Atlantic Ocean, Gulf of Mexico, Caribbean commercial passenger fishing vessel fishery.

NMFS removes both the SC/GA coastal and Southern migratory coastal stocks of bottlenose dolphin from the list of species/stocks incidentally killed or injured in the Category II Southeast Atlantic gillnet fishery.

NMFS removes the Charleston estuarine system stock of bottlenose dolphin from the list of species/stocks incidentally killed or injured in the Category II Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl fishery.

Commercial Fisheries on the High Seas

Fishery Name and Organizational Changes and Clarification

NMFS removes Category II Atlantic Highly Migratory Species trawl fishery from the LOF.

NMFS removes Category II South Pacific tuna fisheries troll fishery from the LOF.

Number of Vessels/Persons

NMFS updates the estimated number of HSFCA permits for high seas fisheries (table 3) as follows:

Category I

- Western Pacific pelagic (HI deep-set component) longline fishery from 150 to 146 HSFCA permits;

Category II

- Pacific highly migratory species drift gillnet fishery from three to two HSFCA permits;
- Western and Central Pacific Ocean tuna purse seine fishery from 34 to 14 HSFCA permits;
- South Pacific albacore troll longline fishery from eight to six HSFCA permits;
- Pacific highly migratory species handline/pole and line fishery from 45 to 36 HSFCA permits;
- South Pacific albacore troll handline/pole and line fishery from seven to one HSFCA permits;
- South Pacific albacore troll fishery from 24 to 23 HSFCA permits;
- Western Pacific pelagic troll fishery from seven to six HSFCA permits;

Category III

- Northwest Atlantic bottom longline fishery from two to one HSFCA permits;
- Pacific highly migratory species longline fishery from 127 to 119 HSFCA permits;

- Pacific highly migratory species purse seine fishery from two to one HSFCA permits;
- Northwest Atlantic trawl fishery from three to one HSFCA permits; and,
- Pacific highly migratory species troll fishery from 93 to 95 HSFCA permits.

List of Species and/or Stocks Incidentally Killed or Injured on the High Seas

NMFS removes the Hawaii stock of striped dolphin from the list of species/stocks incidentally killed or injured in the Category I Western Pacific Pelagic longline fishery (HI deep-set component).

NMFS removes the unknown stock of pygmy killer whale from the list of species/stocks incidentally killed or injured in the Category II Western and Central Pacific Ocean tuna purse seine fishery.

NMFS removes the Hawaii stock of fin whale and Central North Pacific stock of humpback whale from the list of species/stocks incidentally killed or injured in the Category II Western Pacific Pelagic longline fishery (HI shallow-set component).

List of Fisheries

The following tables set forth the list of U.S. commercial fisheries according to their classification under section 118 of the MMPA. Table 1 lists commercial fisheries in the Pacific Ocean (including Alaska), table 2 lists commercial fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean, table 3 lists commercial fisheries on the high seas, and table 4 lists fisheries affected by TRPs or TRTs.

In tables 1 and 2, the estimated number of vessels or persons participating in fisheries operating within U.S. waters is expressed in terms of the number of active participants in the fishery, when possible. If this information is not available, the estimated number of vessels or persons licensed for a particular fishery is provided. If no recent information is available on the number of participants, vessels, or persons licensed in a fishery, then the number from the most recent LOF is used for the estimated number of vessels or persons in the fishery. NMFS acknowledges that, in some cases, these estimates may be inflations of actual effort. For example, the State of Hawaii does not issue fishery-specific licenses, and the number of participants reported in the LOF represents the number of commercial marine license holders who reported using a particular fishing gear type/method at least once in a given year, without considering how many

times the gear was used. For these fisheries, effort by a single participant is counted the same whether the fisherman used the gear only once or every day. In the Mid-Atlantic and New England fisheries, the numbers represent the potential effort for each fishery, given the multiple gear types for which several state permits may allow. Changes made to Mid-Atlantic and New England fishery participants will not affect observer coverage or bycatch estimates, as observer coverage and bycatch estimates are based on vessel trip reports and landings data. Tables 1 and 2 serve to provide a description of the fishery's potential effort (state and Federal). If NMFS is able to gather more accurate information on the gear types used by state permit holders in the future, the numbers will be updated to reflect this change. For additional information on fishing effort in fisheries found on table 1 or 2, contact the relevant regional office (contact information included above in the section: Where can I find more information about the LOF and the MMAP?).

For high seas fisheries, table 3 lists the number of valid HSFCAs permits currently held. Although this likely overestimates the number of active participants in many of these fisheries, the number of valid HSFCAs permits is the most reliable data on the potential effort in high seas fisheries at this time. As noted previously, the number of HSFCAs permits listed in table 3 for the high seas components of fisheries that

also operate within U.S. waters does not necessarily represent additional effort not accounted for in tables 1 and 2. Many vessels holding HSFCAs permits also fish within U.S. waters and are included in the number of vessels and participants operating within those fisheries in tables 1 and 2.

Tables 1, 2, and 3 also list the marine mammal species and/or stocks incidentally killed or injured (seriously or non-seriously) in each fishery based on SARs, injury determination reports, bycatch estimation reports, observer data, logbook data, stranding data, disentanglement network data, fishermen self-reports (*i.e.*, MMAP reports), and anecdotal reports. The best available scientific information included in these reports is based on data through 2020. This list includes all species and/or stocks known to be killed or injured in a given fishery, but also includes species and/or stocks for which there are anecdotal records of a mortality or injury. Additionally, species identified by logbook entries, stranding data, or fishermen self-reports (*i.e.*, MMAP reports) may not be verified. In tables 1 and 2, NMFS has designated those species/stocks driving a fishery's classification (*i.e.*, the fishery is classified based on mortalities and serious injuries of a marine mammal stock that are greater than or equal to 50 percent (Category I), or greater than 1 percent and less than 50 percent (Category II), of a stock's PBR) by including a "1" after the stock's name.

In tables 1 and 2, there are several fisheries classified as Category II that have no recent documented mortalities or serious injuries of marine mammals, or fisheries that did not result in a mortality or serious injury rate greater than 1 percent of a stock's PBR level based on known interactions. NMFS has classified these fisheries by analogy to other Category I or II fisheries that use similar fishing techniques or gear that are known to cause mortality or serious injury of marine mammals, as discussed in the final LOF for 1996 (60 FR 67063, December 28, 1995), and according to factors listed in the definition of a "Category II fishery" in 50 CFR 229.2 (*i.e.*, fishing techniques, gear types, methods used to deter marine mammals, target species, seasons and areas fished, qualitative data from logbooks or fishermen reports, stranding data, and the species and distribution of marine mammals in the area). NMFS has designated those fisheries listed by analogy in tables 1 and 2 by adding a "2" after the fishery's name.

There are several fisheries in tables 1, 2, and 3 in which a portion of the fishing vessels cross the Exclusive Economic Zone (EEZ) boundary and therefore operate both within U.S. waters and on the high seas. These fisheries, though listed separately on tables 1, 2, or 3, are considered the same fisheries on either side of the EEZ boundary. NMFS has designated those fisheries in each table with an asterisk (*) after the fisheries' names.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Category I		
<i>Longline/Set Line Fisheries:</i>		
HI deep-set longline * ^	146	Bottlenose dolphin, HI Pelagic. False killer whale, HI Pelagic. ¹ False killer whale, MHI Insular. False killer whale, NWHI. Kogia spp. (Pygmy or dwarf sperm whale), HI. Risso's dolphin, HI. Rough-toothed dolphin, HI. Short-finned pilot whale, HI.
<i>Gillnet Fisheries:</i>		
AK Southeast salmon drift gillnet	474	Dall's porpoise, AK. Harbor porpoise, northern Southeast Alaska inland waters. Harbor porpoise, southern Southeast Alaska inland waters. ¹ Harbor seal, Southeast AK. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific Pacific white-sided dolphin, North Pacific. Steller sea lion, Eastern U.S.
<i>Pot, Ring Net, and Trap Fisheries:</i>		

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
CA Dungeness crab pot	471	Blue whale, Eastern North Pacific. Gray whale, Eastern North Pacific. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA. Killer whale, Eastern North Pacific GOA, BSAI transient. Killer whale, West Coast transient. Northern elephant seal, CA breeding.
Category II		
<i>Gillnet Fisheries:</i>		
CA thresher shark/swordfish drift gillnet (≥14 in mesh) *	21	Bottlenose dolphin, CA/OR/WA offshore. California sea lion, U.S. Dall's porpoise, CA/OR/WA. Gray whale, Eastern North Pacific. Humpback whale, Central America/Southern Mexico-CA/OR/WA. Humpback whale, Mainland Mexico-CA/OR/WA. Long-beaked common dolphin, CA. Minke whale, CA/OR/WA. Northern elephant seal, CA breeding. Northern right-whale dolphin, CA/OR/WA. Pacific white-sided dolphin, CA/OR/WA. Risso's dolphin, CA/OR/WA. Short-beaked common dolphin, CA/OR/WA. Short-finned pilot whale, CA/OR/WA. ¹ Sperm Whale, CA/OR/WA. ¹
CA halibut/white seabass and other species set gillnet (>3.5 in mesh).	39	California sea lion, U.S. Gray whale, Eastern North Pacific. Harbor seal, CA. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA. Long-beaked common dolphin, CA. Northern elephant seal, CA breeding. Southern sea otter, CA. Short-beaked common dolphin, CA/OR/WA.
CA yellowtail, barracuda, and white seabass drift gillnet (mesh size ≥3.5 in and <14 in) ² .	20	California sea lion, U.S. Long-beaked common dolphin, CA. Short-beaked common dolphin, CA/OR/WA.
AK Bristol Bay salmon drift gillnet ²	1,521	Beluga whale, Bristol Bay. Gray whale, Eastern North Pacific. Harbor seal, Bristol Bay. Northern fur seal, Eastern Pacific. Pacific white-sided dolphin, North Pacific. Spotted seal, Bering. Steller sea lion, Western U.S.
AK Bristol Bay salmon set gillnet ²	855	Beluga whale, Bristol Bay. Gray whale, Eastern North Pacific. Harbor seal, Bristol Bay. Northern fur seal, Eastern Pacific. Spotted seal, Bering.
AK Kodiak salmon set gillnet	128	Harbor porpoise, GOA. ¹ Harbor seal, GOA. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Western North Pacific. Northern sea otter, Southwest AK. Steller sea lion, Western U.S.
AK Cook Inlet salmon set gillnet ²	479	Beluga whale, Cook Inlet. Dall's porpoise, AK. Harbor porpoise, GOA. Harbor seal, Cook Inlet/Shelikof Strait. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Northern sea otter, Southcentral AK. Steller sea lion, Western U.S.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
AK Cook Inlet salmon drift gillnet	355	Beluga whale, Cook Inlet. Dall's porpoise, AK. Harbor porpoise, GOA. ¹ Harbor seal, GOA. Steller sea lion, Western U.S.
AK Peninsula/Aleutian Islands salmon drift gillnet ²	148	Dall's porpoise, AK. Harbor porpoise, GOA. Harbor seal, GOA. Northern fur seal, Eastern Pacific.
AK Peninsula/Aleutian Islands salmon set gillnet ²	75	Harbor porpoise, Bering Sea. Northern sea otter, Southwest AK. Steller sea lion, Western U.S.
AK Prince William Sound salmon drift gillnet	483	Dall's porpoise, AK. Gray whale, Eastern North Pacific. Harbor porpoise, GOA. ¹ Harbor seal, Prince William Sound. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Northern fur seal, Eastern Pacific. Pacific white-sided dolphin, North Pacific. Northern sea otter, Southcentral AK. Steller sea lion, Western U.S. ¹
AK Yakutat salmon set gillnet	95	Gray whale, Eastern North Pacific. Harbor Porpoise, Yakutat/Southeast Alaska offshore waters. ¹ Harbor seal, Southeast AK. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific.
WA Puget Sound Region salmon drift gillnet (includes all inland waters south of US-Canada border and eastward of the Bonilla-Tatoosh line—Treaty Indian fishing is excluded).	136	Dall's porpoise, CA/OR/WA. Harbor porpoise, inland WA. ¹ Harbor seal, WA inland.
<i>Trawl Fisheries:</i>		
AK Bering Sea, Aleutian Islands flatfish trawl	29	Bearded seal, Beringia. Gray whale, Eastern North Pacific. Harbor porpoise, Bering Sea. Harbor seal, Bristol Bay. Humpback whale, Western North Pacific. Killer whale, Eastern North Pacific Alaska resident. ¹ Killer whale, Eastern North Pacific GOA, AI, BS transient. ¹ Northern fur seal, Eastern Pacific. Ringed seal, Arctic. Ribbon seal. Spotted seal, Bering. Steller sea lion, Western U.S. ¹ Walrus, AK.
AK Bering Sea, Aleutian Islands pollock trawl	116	Bearded seal, Beringia. Harbor seal, Bristol Bay. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Western North Pacific. Pacific white-sided dolphin, North Pacific. Ribbon seal. Ringed seal, Arctic. Steller sea lion, Western U.S. ¹
<i>Pot, Ring Net, and Trap Fisheries:</i>		
CA coonstripe shrimp pot	9	Gray whale, Eastern North Pacific. Harbor seal, CA. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA.
CA spiny lobster	189	Bottlenose dolphin, CA/OR/WA offshore. California sea lion, U.S. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA. Gray whale, Eastern North Pacific. Southern sea otter, CA.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
CA spot prawn pot	22	Gray whale, Eastern North Pacific. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA. Long-beaked common dolphin, CA.
OR Dungeness crab pot	323	Gray whale, Eastern North Pacific. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA.
WA/OR/CA sablefish pot	144	Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA. ¹
WA coastal Dungeness crab pot	204	Gray whale, Eastern North Pacific. Humpback whale, Central America/Southern Mexico-CA/OR/WA. ¹ Humpback whale, Mainland Mexico-CA/OR/WA.
<i>Longline/Set Line Fisheries:</i>		
AK Gulf of Alaska sablefish longline	177	Northern elephant seal, California breeding. Sperm whale, North Pacific. ¹ Steller sea lion, Eastern U.S. Steller sea lion, Western U.S.
HI shallow-set longline * ^	14	Bottlenose dolphin, HI Pelagic. False killer whale, HI Pelagic. ¹ Guadalupe fur seal. Risso's dolphin, HI. Striped dolphin, HI.
American Samoa longline ²	11	False killer whale, American Samoa. Rough-toothed dolphin, American Samoa. Striped dolphin, unknown.
HI shortline ²	8	None documented.
<i>Marine Aquaculture Fisheries:</i>		
HI offshore pen culture	1	Hawaiian monk seal.
Category III		
<i>Gillnet Fisheries:</i>		
AK Kuskokwim, Yukon, Norton Sound, Kotzebue salmon gillnet.	360	Harbor porpoise, Bering Sea.
AK Prince William Sound salmon set gillnet	25	Harbor seal, GOA. Northern sea otter, Southcentral AK. Steller sea lion, Western U.S.
AK roe herring and food/bait herring gillnet	15	None documented.
CA herring set gillnet	11	None documented.
HI inshore gillnet	26	Bottlenose dolphin, HI. Spinner dolphin, HI.
WA Grays Harbor salmon drift gillnet (excluding treaty Tribal fishing).	19	Harbor seal, OR/WA coast.
WA/OR Mainstem Columbia River eulachon gillnet	10	None documented.
WA/OR lower Columbia River (includes tributaries) drift net.	244	California sea lion, U.S. Harbor seal, OR/WA coast.
WA Willapa Bay drift gillnet	57	Harbor seal, OR/WA coast. Northern elephant seal, CA breeding.
<i>Miscellaneous Net Fisheries:</i>		
AK Cook Inlet salmon purse seine	16	Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific.
AK Kodiak salmon purse seine	159	Dall's porpoise, AK. Harbor seal, North Kodiak. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Western North Pacific. Steller sea lion, Western U.S.
AK Southeast salmon purse seine	206	Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific.
AK roe herring and food/bait herring purse seine	31	None documented.
AK salmon beach seine	2	None documented.
AK salmon purse seine (Prince William Sound, Chignik, Alaska Peninsula).	298	Harbor seal, GOA. Harbor seal, Prince William Sound.
WA/OR sardine purse seine	6	None documented.
CA anchovy, mackerel, sardine purse seine	53	California sea lion, U.S. Harbor seal, CA.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
CA squid purse seine	68	California sea lion, U.S. Long-beaked common dolphin, CA. Risso's dolphin, CA/OR/WA. Short-beaked common dolphin, CA/OR/WA.
CA tuna purse seine *	14	None documented.
WA/OR Lower Columbia River salmon seine	1	None documented.
WA/OR herring, anchovy, smelt, squid purse seine or lampara	41	None documented.
WA salmon seine	81	None documented.
WA salmon reef net	11	None documented.
HI lift net	14	None documented.
HI inshore purse seine	None recorded	None documented.
HI throw net, cast net	13	None documented.
HI seine net	17	None documented.
<i>Dip Net Fisheries:</i>		
CA squid dip net	19	None documented.
<i>Marine Aquaculture Fisheries:</i>		
CA marine shellfish aquaculture	unknown	None documented.
CA salmon enhancement rearing pen	>1	None documented.
CA white seabass enhancement net pens	13	California sea lion, U.S.
WA salmon net pens	14	California sea lion, U.S. Harbor seal, WA inland waters.
WA/OR shellfish aquaculture	23	None documented.
<i>Troll Fisheries:</i>		
WA/OR/CA albacore surface hook and line/troll	556	None documented.
CA halibut, white seabass, and yellowtail hook and line/handline	388	None documented.
CA/OR/WA non-albacore HMS hook and line	124	None documented.
AK Gulf of Alaska groundfish hand troll and dinglebar troll	4	None documented.
AK salmon troll	850	Steller sea lion, Eastern U.S. Steller sea lion, Western U.S.
American Samoa tuna troll	6	None documented.
CA/OR/WA salmon troll	1,030	None documented.
HI troll	1,124	Pantropical spotted dolphin, HI.
HI rod and reel	235	None documented.
Commonwealth of the Northern Mariana Islands tuna troll	9	None documented.
Guam tuna troll	450	None documented.
<i>Longline/Set Line Fisheries:</i>		
AK Bering Sea, Aleutian Islands Greenland turbot longline	4	Killer whale, GOA, AI, BS transient.
AK Bering Sea, Aleutian Islands Pacific cod longline ...	26	Northern fur seal, Eastern Pacific. Steller sea lion, Western U.S.
AK Bering Sea, Aleutian Islands sablefish longline	8	None documented.
AK Bering Sea, Aleutian Islands halibut longline	84	Northern fur seal, Eastern Pacific. Sperm whale, North Pacific.
AK Gulf of Alaska halibut longline	689	Harbor seal, Clarence Strait. Harbor seal, Cook Inlet. Steller sea lion, Eastern U.S.
AK Gulf of Alaska Pacific cod longline	23	Harbor seal, Cook Inlet/Shelikof Strait. Steller sea lion, Western U.S.
AK octopus/squid longline	0	None documented.
AK state-managed waters longline/setline (including sablefish, rockfish, lingcod, and miscellaneous finfish)	464	None documented.
WA/OR/CA groundfish, bottomfish longline/set line	314	Bottlenose dolphin, CA/OR/WA offshore. California sea lion, U.S. Northern elephant seal, California breeding. Sperm whale, CA/OR/WA. Steller sea lion, Eastern U.S.
WA/OR/CA Pacific halibut longline	130	None documented.
West Coast pelagic longline	4	None documented in the most recent 5 years of data.
HI kaka line	17	None documented.
HI vertical line	6	None documented.
<i>Trawl Fisheries:</i>		
AK Bering Sea, Aleutian Islands Atka mackerel trawl ...	17	Harbor seal, Aleutian Islands. Northern elephant seal, California. Steller sea lion, Western U.S.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
AK Bering Sea, Aleutian Islands Pacific cod trawl	64	Bearded seal, AK. Ribbon seal. Steller sea lion, Western U.S.
AK Bering Sea, Aleutian Islands rockfish trawl	22	Harbor seal, Aleutian Islands. Ribbon seal.
AK Gulf of Alaska flatfish trawl	16	Harbor seal, Cook Inlet/Shelikof Strait. Harbor seal, North Kodiak. Harbor seal, South Kodiak. Steller sea lion, Western U.S.
AK Gulf of Alaska Pacific cod trawl	12	Steller sea lion, Western U.S.
AK Gulf of Alaska pollock trawl	60	Steller sea lion, Western U.S.
AK Gulf of Alaska rockfish trawl	35	Steller sea lion, Western U.S.
AK Kodiak food/bait herring otter trawl	0	None documented.
AK shrimp otter trawl and beam trawl	12	None documented.
CA halibut bottom trawl	23	California sea lion, U.S. Harbor porpoise, unknown. Harbor seal, unknown. Northern elephant seal, CA breeding. Steller sea lion, unknown.
CA sea cucumber trawl	11	California sea lion, U.S.
WA/OR/CA shrimp trawl	130	California sea lion, U.S.
WA/OR/CA groundfish trawl	118	California sea lion, U.S. Dall's porpoise, CA/OR/WA. Harbor seal, OR/WA coast. Northern elephant seal, CA breeding. Northern fur seal, Eastern Pacific. Northern right whale dolphin, CA/OR/WA. Pacific white-sided dolphin, CA/OR/WA. Steller sea lion, Eastern U.S.
<i>Pot, Ring Net, and Trap Fisheries:</i>		
AK Bering Sea, Aleutian Islands Pacific cod pot	80	Harbor seal, Bristol Bay. Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Western North Pacific.
AK Bering Sea, Aleutian Islands sablefish pot	15	Sperm whale, North Pacific.
AK Bering Sea, Aleutian Islands crab pot	73	Bowhead whale, Western Arctic. Gray whale, Eastern North Pacific.
AK Gulf of Alaska crab pot	86	None documented.
AK Gulf of Alaska Pacific cod pot	48	None documented in most recent 5 years of data.
AK Gulf of Alaska sablefish pot	129	None documented.
AK Southeast Alaska crab pot	375	Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Hawai'i.
AK Southeast Alaska shrimp pot	104	Humpback whale, Mexico-North Pacific.
AK shrimp pot, except Southeast	77	None documented.
AK octopus/squid pot	0	None documented.
CA rock crab pot	113	Gray whale, Eastern North Pacific. Harbor seal, CA.
CA Tanner crab pot fishery	1	None documented.
WA/OR/CA hagfish pot	63	None documented.
WA/OR shrimp pot/trap	28	None documented.
WA Puget Sound Dungeness crab pot/trap	145	None documented.
HI crab trap	4	Humpback whale, Hawai'i.
HI fish trap	4	None documented.
HI lobster trap	Less than 3	None documented in recent years.
HI shrimp trap	3	None documented.
HI crab net	4	None documented.
HI Kona crab loop net	13	None documented.
<i>Hook and Line, Handline, and Jig Fisheries:</i>		
AK Bering Sea, Aleutian Islands groundfish jig	2	None documented.
AK Gulf of Alaska groundfish jig	68	None documented in most recent 5 years of data.
AK halibut jig	5	None documented.
American Samoa bottomfish	44	None documented.
Commonwealth of the Northern Mariana Islands bottomfish.	7	None documented.
Guam bottomfish	63	None documented.
HI aku boat, pole, and line	None recorded	None documented.
HI bottomfish handline	392	None documented in recent years.
HI inshore handline	158	None documented.
HI pelagic handline	271	None documented.

TABLE 1—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
WA/OR/CA groundfish/finfish hook and line	689	California sea lion, U.S. Humpback whale, Central America/Southern Mexico-CA/OR/WA. Humpback whale, Mainland Mexico-CA/OR/WA.
Western Pacific squid jig	0	None documented.
<i>Harpoon Fisheries:</i>		
CA swordfish harpoon	21	None documented.
<i>Pound Net/Weir Fisheries:</i>		
AK herring spawn on kelp pound net	143	None documented.
AK Southeast herring roe/food/bait pound net	1	None documented.
HI bulpen trap	< 3	None documented.
<i>Bait Pens:</i>		
WA/OR/CA bait pens	13	California sea lion, U.S.
<i>Dredge Fisheries:</i>		
AK scallop dredge	108 (5 AK)	None documented.
<i>Dive, Hand/Mechanical Collection Fisheries:</i>		
AK clam	57	None documented.
AK miscellaneous invertebrates handpick	188	None documented.
CA/OR/WA dive collection	186	None documented.
CA/WA kelp, seaweed, and algae	4	None documented.
HI black coral diving	None recorded	None documented.
HI fish pond	None recorded	None documented.
HI handpick	25	None documented.
HI lobster diving	12	None documented.
HI spearfishing	67	None documented.
WA/OR/CA hand/mechanical collection	320	None documented.
<i>Commercial Passenger Fishing Vessel (Charter Boat) Fisheries:</i>		
AK/WA/OR/CA commercial passenger fishing vessel ...	>7,000 (1,006 AK)	Humpback whale, Hawai'i. Humpback whale, Mexico-North Pacific. Humpback whale, Western North Pacific. Killer whale, unknown. Steller sea lion, Eastern U.S. Steller sea lion, Western U.S.
<i>Live Finfish/Shellfish Fisheries:</i>		
CA nearshore finfish trap	42	None documented.
HI aquarium collecting	None recorded	None documented.

List of Abbreviations and Symbols Used in table 1: AI—Aleutian Islands; AK—Alaska; BS—Bering Sea; CA—California; ENP—Eastern North Pacific; GOA—Gulf of Alaska; HI—Hawaii; MHI—Main Hawaiian Islands; OR—Oregon; WA—Washington;

¹ Fishery classified based on mortalities and serious injuries of this stock, which are greater than or equal to 50 percent (Category I) or greater than 1 percent and less than 50 percent (Category II) of the stock's PBR;

² Fishery classified by analogy;

* Fishery has an associated high seas component listed in table 3; and

^The list of marine mammal species and/or stocks killed or injured in this fishery is identical to the list of species and/or stocks killed or injured in high seas component of the fishery, minus species and/or stocks that have geographic ranges exclusively on the high seas. The species and/or stocks are found, and the fishery remains the same, on both sides of the EEZ boundary. Therefore, the EEZ components of these fisheries pose the same risk to marine mammals as the components operating on the high seas.

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Category I		
<i>Gillnet Fisheries:</i>		
Mid-Atlantic gillnet	4,020	Bottlenose dolphin, Northern Migratory coastal. Bottlenose dolphin, Southern Migratory coastal. ¹ Bottlenose dolphin, Northern NC estuarine system. ¹ Bottlenose dolphin, Southern NC estuarine system. ¹ Bottlenose dolphin, WNA offshore. Common dolphin, WNA. Gray seal, WNA. Harbor porpoise, GME/BF. Harbor seal, WNA. Harp seal, WNA. Hooded seal, WNA. Humpback whale, Gulf of Maine. Minke whale, Canadian east coast.

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Northeast sink gillnet	4,924	Bottlenose dolphin, Northern Migratory coastal. Bottlenose dolphin, WNA offshore. Common dolphin, WNA. Fin whale, WNA. Gray seal, WNA. ¹ Harbor porpoise, GME/BF. Harbor seal, WNA. Harp seal, WNA. Humpback whale, Gulf of Maine. Minke whale, Canadian east coast. North Atlantic right whale, WNA. Risso's dolphin, WNA. White-sided dolphin, WNA.
<i>Trap/Pot Fisheries:</i> Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot.	8,485	Humpback whale, Gulf of Maine. Minke whale, Canadian east coast. North Atlantic right whale, WNA. ¹
<i>Longline Fisheries:</i> Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline *.	201	Atlantic spotted dolphin, Northern GMX. Bottlenose dolphin, Northern GMX oceanic. Bottlenose dolphin, WNA offshore. Common dolphin, WNA. Cuvier's beaked whale, WNA. False killer whale, WNA. Harbor porpoise, GME, BF. Kogia spp. (Pygmy or dwarf sperm whale), WNA. Long-finned pilot whale, WNA. Mesoplodon beaked whale, WNA. Minke whale, Canadian East coast. Pantropical spotted dolphin, Northern GMX. Pygmy sperm whale, GMX. Risso's dolphin, Northern GMX. Risso's dolphin, WNA. Rough-toothed dolphin, Northern GMX. Short-finned pilot whale, Northern GMX. Short-finned pilot whale, WNA. ¹ Sperm whale, Northern GMX.
Category II		
<i>Gillnet Fisheries:</i> Chesapeake Bay inshore gillnet ²	265	Bottlenose dolphin, unknown (Northern migratory coastal or Southern migratory coastal).
Gulf of Mexico gillnet ²	248	Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, GMX bay, sound, and estuarine. Bottlenose dolphin, Mobile Bay, Bonsecour Bay. Bottlenose dolphin, MS Sound, Lake Borgne, Bay Boudreau. Bottlenose dolphin, Northern GMX coastal. Bottlenose dolphin, Western GMX coastal.
NC inshore gillnet	1,157	Bottlenose dolphin, Northern NC estuarine system. ¹ Bottlenose dolphin, Southern NC estuarine system. ¹
Northeast drift gillnet ²	1,036	None documented.
Southeast Atlantic gillnet ²	273	Bottlenose dolphin, Central FL coastal. Bottlenose dolphin, Northern FL coastal.
Southeastern U.S. Atlantic shark gillnet	21	Bottlenose dolphin, unknown (Central FL, Northern FL, SC/GA coastal, or Southern migratory coastal). North Atlantic right whale, WNA.
<i>Trawl Fisheries:</i> Mid-Atlantic mid-water trawl (including pair trawl)	320	Bottlenose dolphin, WNA offshore. Harbor seal, WNA.
Mid-Atlantic bottom trawl	633	Bottlenose dolphin, WNA offshore. ¹ Common dolphin, WNA. ¹ Gray seal, WNA. ¹ Harbor seal, WNA. Risso's dolphin, WNA. ¹ White-sided dolphin, WNA.

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Northeast mid-water trawl (including pair trawl)	542	Common dolphin, WNA. Gray seal, WNA. Harbor seal, WNA. Long-finned pilot whale, WNA. White-sided dolphin, WNA.
Northeast bottom trawl	968	Bottlenose dolphin, WNA offshore. ¹ Common dolphin, WNA. Gray seal, WNA. ¹ Harbor porpoise, GME/BF. Harbor seal, WNA. Harp seal, WNA. Long-finned pilot whale, WNA. ¹ Risso's dolphin, WNA. ¹ White-sided dolphin, WNA. ¹
Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl	10,824	Atlantic spotted dolphin, Northern Gulf of Mexico. Bottlenose dolphin, Barataria Bay Estuarine System. Bottlenose dolphin, Eastern GMX coastal. ¹ Bottlenose dolphin, GMX bay, sound, estuarine. ¹ Bottlenose dolphin, GMX continental shelf. Bottlenose dolphin, Mississippi River Delta. Bottlenose dolphin, Mobile Bay, Bonsecour Bay. Bottlenose dolphin, Northern GMX coastal. ¹ Bottlenose dolphin, Pensacola Bay, East Bay. Bottlenose dolphin, Perdido Bay. Bottlenose dolphin, SC/GA coastal. ¹ Bottlenose dolphin, Southern migratory coastal. Bottlenose dolphin, Western GMX coastal. ¹
Virginia shrimp trawl	12	None documented.
<i>Trap/Pot Fisheries:</i>		
MA mixed species trap/pot	1,240	None documented.
Southeastern U.S. Atlantic, Gulf of Mexico stone crab trap/pot ² .	1,101	Bottlenose dolphin, Biscayne Bay estuarine. Bottlenose dolphin, Central FL coastal. Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, FL Bay. Bottlenose dolphin, GMX bay, sound, estuarine (FL west coast portion). Bottlenose dolphin, Indian River Lagoon estuarine system. Bottlenose dolphin, Jacksonville estuarine system. Bottlenose dolphin, Sarasota Bay, Little Sarasota Bay.
Atlantic mixed species trap/pot ²	3,493	Fin whale, WNA. Humpback whale, Gulf of Maine.
Atlantic blue crab trap/pot	6,679	Bottlenose dolphin, Biscayne Bay estuarine. Bottlenose dolphin, Central FL coastal. Bottlenose dolphin, Central GA estuarine system. ¹ Bottlenose dolphin, Charleston estuarine system. ¹ Bottlenose dolphin, Indian River Lagoon estuarine system. Bottlenose dolphin, Jacksonville estuarine system. Bottlenose dolphin, Northern FL coastal. ¹ Bottlenose dolphin, Northern GA/Southern SC estuarine system. Bottlenose dolphin, Northern Migratory coastal. Bottlenose dolphin, Northern NC estuarine system. ¹ Bottlenose dolphin, Northern SC estuarine system. Bottlenose dolphin, SC/GA coastal. Bottlenose dolphin, Southern GA estuarine system. Bottlenose dolphin, Southern Migratory coastal. ¹ Bottlenose dolphin, Southern NC estuarine system. West Indian manatee, FL.
<i>Purse Seine Fisheries:</i>		
Gulf of Mexico menhaden purse seine	40–42	Bottlenose dolphin, GMX bay, sound, estuarine. Bottlenose dolphin, Mississippi River Delta. Bottlenose dolphin, Mississippi Sound, Lake Borgne, Bay Boudreau. Bottlenose dolphin, Northern GMX coastal. ¹ Bottlenose dolphin, Western GMX coastal. ¹
Mid-Atlantic menhaden purse seine ²	17	Bottlenose dolphin, Northern Migratory coastal. Bottlenose dolphin, Southern Migratory coastal.
<i>Haul/Beach Seine Fisheries:</i>		

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Mid-Atlantic haul/beach seine	359	Bottlenose dolphin, Northern Migratory coastal. ¹ Bottlenose dolphin, Northern NC estuarine system. ¹ Bottlenose dolphin, Southern Migratory coastal. ¹
NC long haul seine	10	Bottlenose dolphin, Northern NC estuarine system. ¹ Bottlenose dolphin, Southern NC estuarine system.
<i>Stop Seine/Weir/Pound Net:</i> U.S. Mid-Atlantic mixed species stop seine/weir/pound net (except the NC roe mullet stop net).	unknown	Bottlenose dolphin, Northern NC estuarine system.
<i>Stop Net Fisheries:</i> NC roe mullet stop net	1	Bottlenose dolphin, Northern NC estuarine system. Bottlenose dolphin, unknown (Southern migratory coastal or Southern NC estuarine system).
<i>Pound Net Fisheries:</i> VA pound net	20	Bottlenose dolphin, Northern migratory coastal. Bottlenose dolphin, Northern NC estuarine system. Bottlenose dolphin, Southern Migratory coastal. ¹
Category III		
<i>Gillnet Fisheries:</i> Caribbean gillnet	127	None documented in the most recent 5 years of data.
DE River inshore gillnet	unknown	None documented in the most recent 5 years of data.
Long Island Sound inshore gillnet	unknown	None documented in the most recent 5 years of data.
RI, southern MA (to Monomoy Island), and NY Bight (Raritan and Lower NY Bays) inshore gillnet.	unknown	None documented in the most recent 5 years of data.
Southeast Atlantic inshore gillnet	unknown	Bottlenose dolphin, Northern SC estuarine system.
<i>Trawl Fisheries:</i> Atlantic shellfish bottom trawl	>58	None documented.
Gulf of Mexico butterfish trawl	2	Bottlenose dolphin, Northern GMX oceanic. Bottlenose dolphin, Northern GMX continental shelf.
Gulf of Mexico mixed species trawl	20	None documented.
GA cannonball jellyfish trawl	1	Bottlenose dolphin, SC/GA coastal.
<i>Marine Aquaculture Fisheries:</i> Finfish aquaculture	48	Harbor seal, WNA.
Shellfish aquaculture	unknown	None documented.
<i>Purse Seine Fisheries:</i> Gulf of Maine Atlantic herring purse seine	>7	Harbor seal, WNA.
Gulf of Maine menhaden purse seine	>2	None documented.
FL West Coast sardine purse seine	10	None documented.
<i>Longline/Hook and Line Fisheries:</i> Northeast/Mid-Atlantic bottom longline/hook-and-line ...	>1,207	None documented.
Gulf of Maine, U.S. Mid-Atlantic tuna, shark, swordfish hook-and-line/harpoon.	2,846	Humpback whale, Gulf of Maine.
Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean snapper-grouper and other reef fish bottom longline/hook-and-line.	>5,000	Bottlenose dolphin, GMX continental shelf.
Southeastern U.S. Atlantic, Gulf of Mexico shark bottom longline/hook-and-line.	39	Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, Northern GMX continental shelf.
Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean pelagic hook-and-line/harpoon.	680	None documented.
U.S. Atlantic, Gulf of Mexico trotline	unknown	Bottlenose dolphin, Galveston Bay, East Bay, Trinity Bay.
<i>Trap/Pot Fisheries:</i> Caribbean mixed species trap/pot	154	Bottlenose dolphin, Puerto Rico and United States Virgin Islands.
Caribbean spiny lobster trap/pot	40	None documented.
FL spiny lobster trap/pot	1,268	Bottlenose dolphin, Biscayne Bay estuarine. Bottlenose dolphin, Central FL coastal. Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, FL Bay. Bottlenose dolphin, FL Keys.

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Gulf of Mexico blue crab trap/pot	4,113	Bottlenose dolphin, Barataria Bay. Bottlenose dolphin, Caloosahatchee River. Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, GMX bay, sound, estuarine. Bottlenose dolphin, Mississippi Sound, Lake Borgne, Bay Boudreau. Bottlenose dolphin, Mobile Bay, Bonsecour Bay. Bottlenose dolphin, Northern GMX coastal. Bottlenose dolphin, Waccasassa Bay, Withlacoochee Bay, Crystal Bay. Bottlenose dolphin, Western GMX coastal. West Indian manatee, FL.
Gulf of Mexico mixed species trap/pot	unknown	None documented.
Southeastern U.S. Atlantic, Gulf of Mexico golden crab trap/pot.	10	None documented.
U.S. Mid-Atlantic eel trap/pot	unknown	None documented.
<i>Stop Seine/Weir/Pound Net/Floating Trap/Fyke Net Fisheries:</i>		
Gulf of Maine herring and Atlantic mackerel stop seine/weir.	>1	Harbor porpoise, GME/BF. Harbor seal, WNA. Minke whale, Canadian east coast. Atlantic white-sided dolphin, WNA.
U.S. Mid-Atlantic crab stop seine/weir	2,600	None documented.
RI floating trap	9	None documented.
Northeast and Mid-Atlantic fyke net	unknown	None documented.
<i>Dredge Fisheries:</i>		
Gulf of Maine sea urchin dredge	unknown	None documented.
Gulf of Maine mussel dredge	unknown	None documented.
Gulf of Maine, U.S. Mid-Atlantic sea scallop dredge	>403	None documented.
Mid-Atlantic blue crab dredge	unknown	None documented.
Mid-Atlantic soft-shell clam dredge	unknown	None documented.
Mid-Atlantic whelk dredge	unknown	None documented.
U.S. Mid-Atlantic/Gulf of Mexico oyster dredge	7,000	None documented.
New England and Mid-Atlantic offshore surf clam/quahog dredge.	unknown	None documented.
<i>Haul/Beach Seine Fisheries:</i>		
Caribbean haul/beach seine	38	West Indian manatee, Puerto Rico.
Gulf of Mexico haul/beach seine	unknown	None documented.
Southeastern U.S. Atlantic haul/beach seine	25	None documented.
<i>Dive, Hand/Mechanical Collection Fisheries:</i>		
Atlantic Ocean, Gulf of Mexico, Caribbean shellfish dive, hand/mechanical collection.	20,000	None documented.
Gulf of Maine urchin dive, hand/mechanical collection	unknown	None documented.
Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean cast net.	unknown	None documented.
<i>Commercial Passenger Fishing Vessel (Charter Boat) Fisheries:</i>		

TABLE 2—LIST OF FISHERIES—COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery description	Estimated number of vessels/persons	Marine mammal species and/or stocks incidentally killed or injured
Atlantic Ocean, Gulf of Mexico, Caribbean commercial passenger fishing vessel.	4,000	Bottlenose dolphin, Barataria Bay estuarine system. Bottlenose dolphin, Biscayne Bay estuarine. Bottlenose dolphin, Central FL coastal. Bottlenose dolphin, Charleston estuarine system. Bottlenose dolphin, Choctawhatchee Bay. Bottlenose dolphin, Eastern GMX coastal. Bottlenose dolphin, FL Bay. Bottlenose dolphin, GMX bay, sound, estuarine. Bottlenose dolphin, Indian River Lagoon estuarine system. Bottlenose dolphin, Jacksonville estuarine system. Bottlenose dolphin, Mississippi Sound, Lake Borgne, Bay Boudreau. Bottlenose dolphin, Northern FL coastal. Bottlenose dolphin, Northern GA/Southern SC estuarine. Bottlenose dolphin, Northern GMX coastal. Bottlenose dolphin, Northern migratory coastal. Bottlenose dolphin, Northern NC estuarine. Bottlenose dolphin, Southern migratory coastal. Bottlenose dolphin, Southern NC estuarine system. Bottlenose dolphin, SC/GA coastal. Bottlenose dolphin, Western GMX coastal. Short-finned pilot whale, WNA.

List of Abbreviations and Symbols Used in table 2: DE—Delaware; FL—Florida; GA—Georgia; GME/BF—Gulf of Maine/Bay of Fundy; GMX—Gulf of Mexico; MA—Massachusetts; NC—North Carolina; NY—New York; RI—Rhode Island; SC—South Carolina; VA—Virginia; WNA—Western North Atlantic;

¹ Fishery classified based on mortalities and serious injuries of this stock, which are greater than or equal to 50 percent (Category I) or greater than 1 percent and less than 50 percent (Category II) of the stock's PBR;

² Fishery classified by analogy; and

* Fishery has an associated high seas component listed in table 3.

TABLE 3—LIST OF FISHERIES—COMMERCIAL FISHERIES ON THE HIGH SEAS

Fishery description	Number of HSFC permits	Marine mammal species and/or stocks incidentally killed or injured
Category I		
<i>Longline Fisheries:</i>		
Atlantic Highly Migratory Species *	30	Atlantic spotted dolphin, WNA. Bottlenose dolphin, Northern GMX oceanic. Bottlenose dolphin, WNA offshore. Common dolphin, WNA. Cuvier's beaked whale, WNA. False killer whale, WNA. Killer whale, GMX oceanic. Kogia spp. whale (Pygmy or dwarf sperm whale), WNA. Long-finned pilot whale, WNA. Mesoplodon beaked whale, WNA. Minke whale, Canadian East coast. Pantropical spotted dolphin, WNA. Risso's dolphin, GMX. Risso's dolphin, WNA. Short-finned pilot whale, WNA.
Western Pacific Pelagic (HI Deep-set component) * ^	146	Bottlenose dolphin, HI Pelagic. False killer whale, HI Pelagic. Kogia spp. (Pygmy or dwarf sperm whale), HI. Risso's dolphin, HI. Rough-toothed dolphin, HI. Short-finned pilot whale, HI.
Category II		
<i>Drift Gillnet Fisheries:</i>		
Pacific Highly Migratory Species * ^	2	Long-beaked common dolphin, CA. Humpback whale, CA/OR/WA. Northern right-whale dolphin, CA/OR/WA. Pacific white-sided dolphin, CA/OR/WA. Risso's dolphin, CA/OR/WA. Short-beaked common dolphin, CA/OR/WA.

TABLE 3—LIST OF FISHERIES—COMMERCIAL FISHERIES ON THE HIGH SEAS—Continued

Fishery description	Number of HSFC permits	Marine mammal species and/or stocks incidentally killed or injured
<i>Trawl Fisheries:</i>		
CCAMLR	0	Antarctic fur seal.
<i>Purse Seine Fisheries:</i>		
Western and Central Pacific Ocean Tuna Purse Seine	14	Bottlenose dolphin, unknown. Blue whale, unknown. Bryde's whale, unknown. False killer whale, unknown. Fin whale, unknown. Indo-Pacific dolphin. Long-beaked common dolphin, unknown. Melon-headed whale, unknown. Minke whale, unknown. Pantropical spotted dolphin, unknown. Risso's dolphin, unknown. Rough-toothed dolphin, unknown. Sei whale, unknown. Short-finned pilot whale, unknown. Sperm whale, unknown. Spinner dolphin, unknown.
Western Pacific Pelagic	0	No information.
<i>Longline Fisheries:</i>		
CCAMLR	0	None documented.
South Pacific Albacore Troll	6	No information.
Western Pacific Pelagic (HI Shallow-set component) * ^	14	Bottlenose dolphin, HI Pelagic. False killer whale, HI Pelagic. Guadalupe fur seal. Risso's dolphin, HI. Striped dolphin, HI.
<i>Handline/Pole and Line Fisheries:</i>		
Atlantic Highly Migratory Species	0	No information.
Pacific Highly Migratory Species	36	No information.
South Pacific Albacore Troll	1	No information.
Western Pacific Pelagic	1	No information.
<i>Troll Fisheries:</i>		
Atlantic Highly Migratory Species	0	No information.
South Pacific Albacore Troll	23	No information.
Western Pacific Pelagic	6	No information.

Category III

<i>Longline Fisheries:</i>		
Northwest Atlantic Bottom Longline	1	None documented.
Pacific Highly Migratory Species	119	None documented in the most recent 5 years of data.
<i>Purse Seine Fisheries:</i>		
Pacific Highly Migratory Species * ^	1	None documented.
<i>Trawl Fisheries:</i>		
Northwest Atlantic	1	None documented.
<i>Troll Fisheries:</i>		
Pacific Highly Migratory Species *	95	None documented.

List of Terms, Abbreviations, and Symbols Used in table 3: CA—California; GMX—Gulf of Mexico; HI—Hawaii; OR—Oregon; WA—Washington; WNA—Western North Atlantic;

*Fishery is an extension/component of an existing fishery operating within U.S. waters listed in table 1 or 2. The number of permits listed in table 3 represents only the number of permits for the high seas component of the fishery; and

^The list of marine mammal species and/or stocks killed or injured in this fishery is identical to the list of marine mammal species and/or stocks killed or injured in U.S. waters component of the fishery, minus species and/or stocks that have geographic ranges exclusively in coastal waters, because the marine mammal species and/or stocks are also found on the high seas and the fishery remains the same on both sides of the EEZ boundary. Therefore, the high seas components of these fisheries pose the same risk to marine mammals as the components of these fisheries operating in U.S. waters.

TABLE 4—FISHERIES AFFECTED BY TAKE REDUCTION TEAMS AND PLANS

Take reduction plans	Affected fisheries
Atlantic Large Whale Take Reduction Plan (ALWTRP)—50 CFR 229.32	<i>Category I:</i> Mid-Atlantic gillnet. Northeast/Mid-Atlantic American lobster and Jonah crab trap/pot. Northeast sink gillnet.

TABLE 4—FISHERIES AFFECTED BY TAKE REDUCTION TEAMS AND PLANS—Continued

Take reduction plans	Affected fisheries
Bottlenose Dolphin Take Reduction Plan (BDTRP)—50 CFR 229.35	<p><i>Category II:</i></p> <p>Atlantic blue crab trap/pot. Atlantic mixed species trap/pot. MA mixed species trap/pot. Northeast drift gillnet. Southeast Atlantic gillnet. Southeastern U.S. Atlantic shark gillnet.* Southeastern, U.S. Atlantic, Gulf of Mexico stone crab trap/pot.^</p> <p><i>Category I:</i></p> <p>Mid-Atlantic gillnet.</p> <p><i>Category II:</i></p> <p>Atlantic blue crab trap/pot. Chesapeake Bay inshore gillnet fishery. Mid-Atlantic haul/beach seine. Mid-Atlantic menhaden purse seine. NC inshore gillnet. NC long haul seine. NC roe mullet stop net. Southeast Atlantic gillnet. Southeastern U.S. Atlantic shark gillnet. Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl.^ Southeastern, U.S. Atlantic, Gulf of Mexico stone crab trap/pot.^ U.S. Mid-Atlantic mixed species stop seine/weir/pound net (except the NC roe mullet stop net). VA pound net.</p>
False Killer Whale Take Reduction Plan (FKWTRP)—50 CFR 229.37 ..	<p><i>Category I:</i></p> <p>HI deep-set longline.</p> <p><i>Category II:</i></p> <p>HI shallow-set longline.</p>
Harbor Porpoise Take Reduction Plan (HPTRP)—50 CFR 229.33 (New England) and 229.34 (Mid-Atlantic).	<p><i>Category I:</i></p> <p>Mid-Atlantic gillnet. Northeast sink gillnet.</p>
Pelagic Longline Take Reduction Plan (PLTRP)—50 CFR 229.36	<p><i>Category I:</i></p> <p>Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline.</p>
Pacific Offshore Cetacean Take Reduction Plan (POCTRP)—50 CFR 229.31.	<p><i>Category II:</i></p> <p>CA thresher shark/swordfish drift gillnet (≥14 in mesh).</p>
Atlantic Trawl Gear Take Reduction Team (ATGTRT)	<p><i>Category II:</i></p> <p>Mid-Atlantic bottom trawl. Mid-Atlantic mid-water trawl (including pair trawl). Northeast bottom trawl. Northeast mid-water trawl (including pair trawl).</p>

List of Symbols Used in table 4:

* Only applicable to the portion of the fishery operating in U.S. waters; and

^ Only applicable to the portion of the fishery operating in the Atlantic Ocean

Classification

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) at the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. No comments were received on that certification, and no new information has been discovered to change that conclusion. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

This rule contains existing collection-of-information (COI) requirements subject to the Paperwork Reduction Act but would not impose additional or new COI requirements. The COI for the registration of individuals under the MMPA has been approved by the Office of Management and Budget (OMB)

under OMB Control Number 0648–0293 (0.15 hours per report for new registrants). The requirement for reporting marine mammal mortalities or injuries has been approved by OMB under OMB Control Number 0648–0292 (0.15 hours per report). These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the COI. Send comments regarding these reporting burden estimates or any other aspect of the COI, including suggestions for reducing burden, to NMFS (see **ADDRESSES**). You may also submit comments on these or any other aspects of the collection of information at <https://www.reginfo.gov/public/do/PRAMain>.

Notwithstanding any other provision of law, no person is required to respond

to, nor shall a person be subject to a penalty for failure to comply with, a COI, subject to the requirements of the Paperwork Reduction Act, unless that COI displays a currently valid OMB control number.

This rule has been determined to be not significant for the purposes of Executive Orders 12866 and 13563.

In accordance with the Companion Manual for NOAA Administrative Order (NAO) 216–6A, NMFS determined that the publication of this LOF qualifies to be categorically excluded from further NEPA review, consistent with categories of activities identified in Categorical Exclusion G7 (“Preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature, or for which the environmental effects are too broad, speculative or conjectural to lend themselves to

meaningful analysis and will be subject later to the NEPA process, either collectively or on a case-by-case basis”) of the Companion Manual and we have not identified any extraordinary circumstances listed in Chapter 4 of the Companion Manual for NAO 216–6A that would preclude application of this categorical exclusion. If NMFS takes a management action, for example, through the development of a TRP, NMFS would first prepare an Environmental Impact Statement or Environmental Assessment, as required under NEPA, specific to that action.

This rule would not affect species listed as threatened or endangered under the ESA or their associated critical habitat. The impacts of numerous fisheries have been analyzed in various biological opinions, and this rule will not affect the conclusions of those opinions. The classification of fisheries on the LOF is not considered to be a management action that would adversely affect threatened or endangered species. If NMFS takes a management action, for example, through the development of a TRP, NMFS would consult under ESA section 7 on that action.

This rule would have no adverse impacts on marine mammals and may have a positive impact on marine mammals by improving knowledge of marine mammals and the fisheries interacting with marine mammals through information collected from observer programs, stranding and sighting data, or take reduction teams.

This rule would not affect the land or water uses or natural resources of the coastal zone, as specified under section 307 of the Coastal Zone Management Act.

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Dated: February 9, 2024.

Samuel D. Rauch, III,
Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 240212–0045]

RIN 0648–BL70

Magnuson-Stevens Act Provisions; Prohibition of Commercial Fishing in the Northeast Canyons and Seamounts Marine National Monument

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This action implements regulations for the Northeast Canyons and Seamounts Marine National Monument. This action is necessary to conform U.S. fishing regulations to be consistent with Presidential Proclamations 9496 and 10287, which

prohibited commercial fishing in the Northeast Canyons and Seamounts Marine National Monument and directed the Secretaries of Commerce and Interior to promulgate regulations necessary for the proper care and management of the Monument. The measures herein are intended to define the boundary coordinates of the Monument area and clarify the prohibition on commercial fishing in the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) regulations.

DATES: Effective March 18, 2024.

FOR FURTHER INFORMATION CONTACT: Laura Deighan, Fishery Management Specialist, 978–281–9184.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 2016, the Northeast Canyons and Seamounts Marine Monument was designated in the waters of the North Atlantic (Presidential Proclamation 9496; 81 FR 65161, September 21, 2016), to include both a Canyons Unit and a Seamounts Unit. This Proclamation prohibited commercial fishing within the Monument, with a 7-year exemption for the American lobster and Atlantic deep-sea red crab fisheries. In June 2020, Monument prohibitions were revised via Proclamation 10049 (85 FR 35793, June 11, 2020) removing commercial fishing from the list of prohibited activities set forth in the 2016 Proclamation. Most recently, in October 2021, Proclamation 10287 (86 FR 57349, October 15, 2021) restored commercial fishing to the list of prohibited activities, providing “for the prohibition of all commercial fishing in the Monument, except for red crab and American lobster commercial fishing, which may be permitted until September 15, 2023.”

Approved Measures

Consistent with Proclamation 10287 (68 FR 57349, October 15, 2021) and the requirements of the Magnuson-Stevens Act, this action defines the boundary coordinates of the Monument area in the Magnuson-Stevens Act regulations at 50 CFR 600.10. Tables 1 and 2 below include coordinates for the Canyons and Seamounts Units.

TABLE 1—CANYONS UNIT COORDINATES

Point	N Latitude	W Longitude
1	40°31.62'	68°16.08'
2	40°36.00'	67°37.68'
3	40°12.42'	67°34.68'
4	40°7.32'	68°12.72'

TABLE 1—CANYONS UNIT
COORDINATES—Continued

Point	N Latitude	W Longitude
1	40°31.62'	68°16.08'

TABLE 2—SEAMOUNTS UNIT
COORDINATES

Point	N Latitude	W Longitude
1	40°2.64'	67°43.32'
2	39°56.34'	(a)
3	38°51.90'	(b)
1	40°2.64'	67°43.32'

^aU.S. exclusive economic zone (EEZ) longitude, approximately 65°56.58'.

^bU.S. EEZ longitude, approximately 66°55.86'.

This rule also reflects Proclamation 10287's prohibition on commercial fishing within the boundaries of the Monument in the Magnuson-Stevens Act prohibitions at § 600.725 and clarifies that commercial fishermen may transit through the Monument if fishing gear is stowed and not available for immediate use during passage through the Monument.

Comments and Responses

We published a proposed rule in the **Federal Register** on October 19, 2023 (88 FR 72038), soliciting public comment. The comment period ended on November 20, 2023. We received a total of 11,640 comments submitted by 6 individual commercial and recreational fishermen; 2 academics and researchers; 11,589 members of the public; and 40 environmental, 2 commercial fishing, and 1 legal organization. One comment related to wind development, which is not the subject of this action, and is not discussed further. A more detailed summary of the relevant comments and our responses is provided below.

Establishment of the Monument and Its Commercial Fishing Prohibition

Comment 1: A total of seven commenters—four individual fishermen, two members of the public, and one commercial fishing organization—expressed general opposition to the action because (1) the commercial fishing prohibition results in the loss of an important fishing ground; (2) the commercial fishing prohibition will have a negative impact on fisheries in general or on pelagic longline and highly migratory species fisheries specifically; (3) the loss of fishing opportunity for species managed multilaterally by the International Commission for the Conservation of Atlantic Tunas may result in reductions

of U.S. quota, reallocated to countries with less sustainable management; (4) the commercial fishing prohibition gives exclusive access to recreational fisheries, and the area should either be closed or open to all fisheries without any exceptions; (5) recreational fisheries do not have the same level of monitoring as commercial fisheries; (6) marine protected areas are the least effective fisheries management tool and fail to recognize biology and ecology, are not adaptive, and force vessels to fish in less desirable areas; (7) fisheries that do not interact with benthic habitat and/or that have sufficient monitoring in place should be allowed to fish in the Monument; (8) “objects of historic or scientific interest,” which the Antiquities Act of 1906 (54 U.S.C. 320301–320303) was established to protect, does not include living marine resources; (9) the Monument does not represent the “smallest area compatible” with the proper care and management of the objects the Monument was established to protect, as required under the Antiquities Act; (10) the Monument does not provide proper care and management of highly migratory species, which have a much larger range than the Monument; (11) the establishment of the Monument was not based on the best scientific information available; and (12) the commercial fishing prohibition poses prosecution risk to members of industry if gear drifts, and vessels will not be able to set gear near the Monument because of this risk.

A total of 11,627 commenters—11,584 members of the public, 2 individual fishermen, 1 individual researcher, and 40 environmental organizations—expressed general support for the Monument for reasons including the Monument is a relatively small area, it is a unique area, it is in need of protection, it supports sustainable fisheries, and it balances conservation and economics. One comment further stated that the Monument should be fully protected and all fishing activity should be prohibited within its boundaries.

Response: These comments address the establishment of the Monument and its associated commercial fishing prohibition, which were implemented through Presidential Proclamations 10287 and 9496. NMFS does not establish, initiate, or control the marine monument process. Under the Antiquities Act, the President establishes marine monuments and makes the final decision on what is protected and what uses will be restricted upon establishment.

Monument Management Plan

Comment 2: Two comments submitted by commercial fishing organizations criticize the development of the draft Management Plan, the lack of public involvement in its development, and the likelihood of its development having a substantial cost and little benefit.

Response: This rulemaking is separate and distinct from the development of the draft Management Plan. Further, NMFS is not primarily responsible for the Management Plan's development. The U.S. Fish and Wildlife Service is the lead agency responsible for the draft Management Plan.

Legal Basis and Procedures

Comment 3: One comment submitted by an organization asserts that NMFS' prohibition on commercial fishing in an area of the Atlantic Ocean is based on an “illegal” Presidential Proclamation issued under the Antiquities Act. The comment states that the Proclamation exceeds the President's authority under the Antiquities Act and violates the U.S. Constitution's separation of powers. Thus, it argues that any agency action, including this action seeking to include the Monument and the commercial fishing prohibition in the Magnuson-Stevens Act regulations, is, among other legal flaws, arbitrary, capricious, and not in accordance with law. Further, it asserts that the Monument's prohibition on commercial fishing is outside the President's authority under the Antiquities Act and that any agency action, including this rulemaking, taken in furtherance of the Monument designation would violate the Administrative Procedure Act (APA).

Response: The Monument Proclamations 9496 and 10287 are within the President's authority under the Antiquities Act, and this rule is consistent with the APA. NMFS is an agency of the Executive Branch and thus is required to comply with directives from the President. The President prohibited commercial fishing in the Monument in the most recent Proclamation, Proclamation 10287. The Proclamation further directs NMFS to implement the existing prohibition on commercial fishing within the Monument.

Section 305(d) of the Magnuson-Stevens Act provides that “The Secretary shall have general responsibility to carry out any fishery management plan (FMP) or amendment approved or prepared by him, in accordance with the provisions of this Act. The Secretary may promulgate such regulations, in accordance with section

553 of Title 5, United States Code, as may be necessary to discharge such responsibility or to carry out any other provision of this Act” (emphasis added).

NMFS is responding to a change in law stemming from the Antiquities Act. Proclamation 10287’s prohibition on commercial fishing is “existing law,” and section 303(a)(1)(C) of the Magnuson-Stevens Act requires FMPs to be “consistent with . . . any other applicable law.” (Emphasis added). Including the prohibition against fishing in the Monument in the Magnuson-Stevens Act regulations is consistent with existing law established by the Proclamation. It should be noted that both the New England and Mid-Atlantic Fishery Management Councils were invited to act to implement the Proclamation’s prohibition on commercial fishing, and both declined.

Comment 4: One comment, submitted by a legal organization, states that the rule seeks to “conform” Magnuson-Stevens Act regulations to the Proclamation’s commercial fishing prohibition within the Monument but, the commenter states, to prohibit commercial fishing under the Magnuson-Stevens Act, NMFS must conform to the statutory requirements enacted by Congress in the Magnuson-Stevens Act. The commenter believes NMFS has “ignored its duty and provided no analysis under the Magnuson-Stevens Act. Thus, the rule is, among other legal flaws, arbitrary, capricious, and not in accordance with law.” A second comment, submitted by a commercial fishing organization, similarly stated that the rule should have included Magnuson-Stevens Act process requirements and National Standard considerations.

Response: Proclamation 10287 prohibited commercial fishing in the Monument on October 8, 2021. The prohibition went into effect immediately (with exceptions for red crab and lobster fishing until September 15, 2023).

As discussed above, the use of Magnuson-Stevens Act section 305(d) is necessary to ensure FMPs are consistent with all applicable law, in accordance with section 303(a)(1)(C). In addition, the placement of these regulations in the overarching Magnuson-Stevens Act regulations at part 600 ensures that all existing and future FMPs (*i.e.*, not solely Greater Atlantic Region management plans) conform to section 303(a)(1)(C)’s mandate that plans are consistent with other applicable law.

This action is not discretionary and this rule does not impose a restriction or prohibition on commercial fishing in the Monument. The restriction and

prohibition on commercial fishing within the Monument exists even in the absence of this rule. This rule is necessary to document within regulation the boundary coordinates of the Monument area so that the fishing industry and public can be informed as to the location of the Monument in order to comply with the commercial fishing prohibition. This rule is also necessary to document the prohibition on commercial fishing within the Monument and to ensure the commercial fishing industry and public are aware that commercial fishing vessels may transit the Monument provided that all fishing gear is stowed and unavailable for immediate use. This rule serves to ensure the commercial fishing industry has the information necessary to comply with the provisions of the Proclamation without being overburdened either due to uncertainty as to the boundary coordinates of the Monument area or uncertainty regarding whether transiting the Monument is authorized.

Comment 5: Four comments submitted by environmental organizations expressed support for the inclusion of the Monument commercial fishing prohibition into the Magnuson-Stevens Act regulations. Three of the four comments provided the reasoning that the action fulfills the requirement in section 303(a)(1)(C) that FMPs be consistent with other applicable laws, in this case the Antiquities Act and Presidential Proclamations 10287 and 9496. Two of them provided further rationale that the action is consistent with section 305(d) of the Magnuson-Stevens Act. One of the comments did not provide further reasoning.

Response: NMFS agrees that section 303(a)(1)(C) of the Magnuson-Stevens Act requires FMPs to be consistent with other applicable laws and is implementing this action under the Secretarial authority at section 305(d).

Comment 6: One comment from a legal organization states that this rulemaking skirts NMFS’ duty to conduct a regulatory flexibility analysis under the Regulatory Flexibility Act (RFA). When an agency publishes a general notice of proposed rulemaking, the RFA usually requires the agency to prepare and make available for public comment an initial regulatory flexibility analysis (IRFA), which describes the effect a proposed rule will have on small entities. The commenter asserts that the lack of an IRFA for this proposed rule violates the RFA because it is based on the President’s illegal action to prohibit commercial fishing in the Monument.

Response: The RFA generally requires that, when an agency publishes a proposed rule, as NMFS has done here, it must also “prepare and make available for public comment” an IRFA, that describes “the impact of the proposed rule on small entities” and also seek out and describe less burdensome alternatives to the proposed rule. However, because the Monument has been closed to commercial fishing by Proclamation 10287 since October 2021, this rule will have no additional effect on regulated entities beyond what is already in place. Moreover, the Proclamation’s directive to NMFS to implement the commercial fishing prohibition gives the agency no discretion to consider or implement any alternatives. Therefore, NMFS cannot describe less burdensome alternatives to implementing the existing prohibition on commercial fishing, because there are no less burdensome alternatives.

While NMFS did not prepare an IRFA, it did comply with the RFA. Section 605(b) of the RFA indicates that the preparation of an IRFA or final regulatory flexibility analysis is not required for rules that “will not, if promulgated, have a significant economic impact on a substantial number of small entities,” as certified by the head of the agency. In such cases, the agency is required to publish the certification, along with the factual basis for the certification, in the **Federal Register** with the notice of proposed rulemaking or the final rule. The proposed rule included the factual basis for this determination, as certified to the SBA Office of Advocacy by the Chief Counsel for Regulation of the Department of Commerce, which demonstrates that while entities will be subject to this action, they are already subject to the commercial fishing prohibition, and, therefore, this action has no additional effect on these regulated entities.

Comment 7: One comment from a commercial fishing organization states that taking this action pursuant to an Executive Order citing the Antiquities Act, instead of using the processes established in the Magnuson-Stevens Act for closures and other actions, and the lack of any analysis under the National Environmental Policy Act (NEPA), are “the antithesis of good governance” and decries the lack of public involvement. However, the comment goes on to state: “We understand that NMFS has no discretion regarding this action; in fact, the docket clearly articulates this: ‘Because this action serves to bring the Magnuson-Stevens Act regulations into compliance with Presidential Proclamations 9496

and 10287, there is no decision-making process for NMFS. NMFS has no discretion. As a result, there is no decision-making process, no alternatives to comply with the Proclamations, and no public involvement in the decision. There is no “proposal” for action, as defined in section 1501.1(a)(5) of the Council on Environmental Quality regulations implementing the NEPA. Therefore, NEPA does not apply to this action.’ We understand this and therefore cannot argue against NMFS compliance with the Executive Orders as detailed in the Proposed Rule.”

Response: We agree with these comments regarding NMFS’ lack of discretion in proposing this rule in compliance with the Proclamations’ requirements. The President established the Monument and prohibited fishing in the Monument.

Economic Impacts of the Monument and This Action

Comment 8: We received one comment from an individual researcher and two comments from environmental organizations related to the impacts of the Monument that, based on analyses submitted as part of one comment, there is little evidence that the commercial fishing prohibition had significant economic impacts on commercial fisheries. The two environmental organizations also commented that the inclusion of the commercial fishing prohibition into the Magnuson-Stevens Act regulations would not have additional effects on regulated entities because the area is already closed to commercial fishing by Presidential Proclamations 10287 and 9496.

Response: NMFS agrees that this action will have no additional effect on regulated entities because fishing was previously prohibited in the Monument.

Opportunities for Public Participation

Comment 9: One environmental organization noted that the Monument process has included several opportunities for public participation, including the comment period on this rulemaking and additional comment periods related to the Monument (e.g., prior to its designation, throughout the development of a management plan, at New England Fishery Management Council meetings).

Response: This rulemaking included an opportunity for public participation through the publication of a proposed rule in the **Federal Register** on October 19, 2023 (88 FR 72038), soliciting public comment. The comment period ended on November 20, 2023. Other actions, including the Monument’s establishment through Presidential

Proclamation 9496 and the development of a management plan and public input submitted in response to those actions are separate and distinct from this rulemaking.

Requests for Additional Information

Comment 10: Two comments submitted by members of the public asked how the fishing prohibition would be enforced, in general or in regard to foreign fishing fleets.

Response: The commercial fishing prohibition in the Monument will be enforced with the same resources and tools that are used to enforce other existing closures and gear-restricted areas, including enforcement patrols and vessel monitoring and reporting requirements.

Comment 11: One member of the public stated that the reason for the 7-year phase-out for lobster and red crab is unclear and asked whether there would be regulations limiting the number of lobster and crab pots and specifying the type of rope used in the Monument for these fisheries.

Response: The 7-year phase-out for lobster and red crab was established by Presidential Proclamations 9496 and 10287. Under the Antiquities Act, the President establishes marine monuments and makes the final decision on what is protected and what uses will be restricted upon establishment. NMFS does not establish, initiate, or control the marine monument process. Presidential Proclamation 10287 established September 15, 2023, as the end of the phase-out period, and all commercial fishing is currently prohibited in the Monument by Presidential Proclamation. This action adds the commercial fishing prohibition within the Monument to the list of prohibited activities at § 600.725 and does not make any exceptions or differing regulations for the lobster or red crab fisheries. While lobster and Jonah crab are managed under the Atlantic Coastal Fisheries Cooperative Management Act with implementing regulations at part 697, this action applies to the lobster and Jonah crab fisheries. The definitions (§ 697.2(a)) and prohibitions for lobster (§ 697.7(c)(1)) and Jonah crab (§ 697.7(h)) state that the Magnuson-Stevens Act definitions at § 600.10 and prohibitions at § 600.725 are also applicable to these fisheries.

Comment 12: One member of the public commented that it is unclear why NEPA didn’t apply, as a “proposal” is being made and a change in activities allowed is also being implemented.

Response: Section 1501.1(a)(d) of the Council on Environmental Quality

regulations implementing NEPA states that an agency should consider “whether the proposed activity or decision, in whole or in part, is a non-discretionary action for which the agency lacks authority to consider environmental effects as part of its decision-making process” when determining whether NEPA applies. NMFS does not establish, initiate, or control the marine monument process. The President established the Monument under the Antiquities Act and made the final decision on what is protected and what uses are restricted within the Monument. Because this action serves to bring the Magnuson-Stevens Act regulations into compliance with Presidential Proclamations 9496 and 10287, there is no decision-making process for NMFS. NMFS has no discretion. Therefore, NEPA does not apply to this action.

Requests for Additions to the Administrative Record

Comment 13: One comment from an individual researcher requested that the administrative record include three scientific analyses of fishing activity in the Monument (Lynham, J., *Fishing Activity Before Closure, During Closure, and After Reopening of the Northeast Canyons and Seamounts Marine National Monument*. Sci. Reports 12, 1–21 (2022).; Lynham, J., *The Northeast Canyons & Seamounts Marine National Monument and the Atlantic Deep-Sea Red Crab Fishery*, Unpublished, 1–14.; Lynham, J., *The Northeast Canyons & Seamounts Marine National Monument and the Atlantic Lobster Fishery*, Unpublished, 1–15.) and one comment from a commercial fishing organization requested that it include comments it previously submitted in response to a Notice of Intent to Conduct Scoping and to Prepare a Draft Environmental Impact Statement for the Proposed Hudson Canyon National Marine Sanctuary (87 FR 34853, June 8, 2022) and a Review of Certain National Monuments Established Since 1996; Notice of Opportunity for Public Comment (82 FR 22016, May 11, 2017) and two scientific publications (Hampton J, Lehodey P, Senina I, Nicol S, Scutt Phillips J and Tiamere K (2023), *Limited Conservation Efficacy of Large-scale Marine Protected Areas for Pacific Skipjack and Bigeye Tunas*. Front. Mar. Sci. 9:1060943. doi: 10.3389/fmars.2022.1060943. Hilborn, R., Kaiser, M.J., *A Path Forward for Analysing the Impacts of Marine Protected Areas*. Nature 607, E1–E2 (2022). <https://doi.org/10.1038/s41586-022-04775-1>).

Response: As comments, including attachments and hyperlinked references,

are part of the administrative record, the subject analyses and comments have been added to the administrative record for this action.

Classification

NMFS is issuing this rule pursuant to section 305(d) of the Magnuson-Stevens Act to comply with section 303(a)(1)(C) by promulgating regulations (at §§ 600.10 and 600.725) to ensure that all FMPs implemented by the Secretary of Commerce are consistent with, and conform to, the Proclamations and the Antiquities Act by ensuring clearly articulated measures that apply to all commercial fishing vessels operating in the EEZ. The NMFS Assistant Administrator has determined that this rule is consistent with other applicable law.

Because this action serves to bring the Magnuson-Stevens Act regulations into compliance with Presidential Proclamations 9496 and 10287, there is no decision-making process for NMFS. NMFS has no discretion. As a result, there is no decision-making process, no alternatives to comply with the Proclamations, and no public involvement in the decision. There is no “proposal” for action, as defined in section 1501.1(a)(5) of the Council on Environmental Quality regulations implementing NEPA. Therefore, NEPA does not apply to this action.

This rule has been determined not to be significant for purposes of Executive Order 12866.

Regulatory Flexibility Act (RFA)

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here.

We received one comment regarding requirements under the RFA. The comment did not contest the factual basis for the certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 600

Fisheries, Fishing.

Dated: February 13, 2024.

Samuel D. Rauch III,
Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 600 to read as follows:

PART 600—MAGNUSON—STEVENS
ACT PROVISIONS

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 et seq.

■ 2. In § 600.10, add the definition for “Northeast Canyons and Seamounts Marine National Monument” as follows:

§ 600.10 Definitions.

* * * * *

Northeast Canyons and Seamounts Marine National Monument means the area designated by Presidential Proclamation 9496, consisting of:

(1) Canyons Unit. The Canyons Unit is defined by the area bounded by straight lines connecting the following points, in the order stated:

Point	N Latitude	W Longitude
1	40°31.62'	68°16.08'
2	40°36.00'	67°37.68'
3	40°12.42'	67°34.68'
4	40°7.32'	68°12.72'
1	40°31.62'	68°16.08'

(2) Seamounts Unit. The Seamounts Unit is defined by the area bounded by straight lines connecting the following points, except between points 1 and 2, where the boundary follows the outer limits of the U.S. EEZ:

Point	N Latitude	W Longitude
1	40°2.64'	67°43.32'
2	39°56.34'	(a)
3	38°51.90'	(b)
1	40°2.64'	67°43.32'

^a U.S. EEZ longitude, approximately 65°56.58'.

^b U.S. EEZ longitude, approximately 66°55.86'.

* * * * *

■ 3. In § 600.725, add paragraph (x) to read as follows:

§ 600.725 General prohibitions.

* * * * *

(x) Fish for commercial purposes within the Northeast Canyons and Seamounts Marine National Monument, as defined in § 600.10, consistent with Presidential Proclamations 9496 and 10287. Fishing for commercial purposes means fishing that is intended to, or results in, the barter, trade, transfer, or sale of fish, either in whole or in part.

(1) Vessels may transit the Northeast Canyons and Seamounts Marine National Monument, provided commercial fishing gear is stowed and not available for immediate use during passage without interruption through the Northeast Canyons and Seamounts Marine National Monument.

(2) [Reserved]

* * * * *

[FR Doc. 2024–03247 Filed 2–15–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 89, No. 33

Friday, February 16, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Parts 2471 and 2472

Procedures of the Panel; Miscellaneous Requirements

AGENCY: Federal Service Impasses Panel, Federal Labor Relations Authority.

ACTION: Proposed rule.

SUMMARY: The Federal Labor Relations Authority's (FLRA) Federal Service Impasses Panel (FSIP) is proposing updates to its regulations to establish revised methods by which the public may obtain specific forms from the FSIP, and then file, or formally submit, those forms and other documents during the course of FSIP proceedings.

DATES: Written comments must be received on or before March 18, 2024.

ADDRESSES: You may send comments, which must include the caption "FSIP Procedures of the Panel; Miscellaneous Requirements," by one of the following methods:

Email: SolMail@flra.gov. Include "FSIP Procedures of the Panel; Miscellaneous Requirements" in the subject line of the message.

Mail: Thomas Tso, Solicitor, Federal Labor Relations Authority, 1400 K Street NW, Suite 300, Washington, DC 20424-0001.

Instructions: Do not mail written comments if they have been submitted via email. Interested persons who mail written comments must submit an original and 4 copies of each written comment, with any enclosures, on 8½ x 11 inch paper. Do not deliver comments by hand.

FOR FURTHER INFORMATION CONTACT: Kimberly Moseley, Executive Director, Federal Service Impasses Panel, at kmoseley@flra.gov or at: 771-444-5765.

SUPPLEMENTARY INFORMATION: Due primarily to budgetary constraints, the Federal Labor Relations Authority (FLRA), including FSIP, is consolidating its office space at 1400 K Street NW,

Washington, DC, so that all of the offices currently on the second floor of that address will now be located on the third floor, along with the other FLRA offices that are already located on the third floor. Additionally, as FSIP continues to move towards fully electronic case files, it wishes to strongly encourage parties to file any permissible documents through the eFiling system, and to implement a requirement that allows in-person filing of forms or documents in FSIP matters by permission only, at an appointed time. To the extent that moving to an "appointment-only" in-person filing system has any effect at all on parties' filing practices, it should promote eFiling. Further, it would assist FSIP—which has currently a staff of only four employees—in more easily managing staff-coverage issues, especially if budget constraints or other considerations prevent it from filling vacancies as they arise.

Given these considerations, the FSIP proposes to amend 5 CFR parts 2471.2, 2471.5, 2472.3, 2472.5, and 2472.6 to update procedures for obtaining FSIP-specific forms and then filing or formally submitting those forms and other documents during the course of proceedings before the FSIP. The proposed amendments would promote eFiling, and conserve FSIP staff's time and efficiency by allowing staff members to accept documents after giving advance permission, and at specific appointed times. This arrangement will allow staff members to avoid remaining on constant stand-by for lengthy periods of time each week to accept forms and documents, thus losing the opportunity to perform other critical tasks.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Chairman of the FSIP has determined that this proposed rule will not have a significant impact on a substantial number of small entities, because this proposed rule applies only to Federal agencies, Federal employees, and labor organizations representing those employees.

Executive Order 12866, Regulatory Review

The FLRA is an independent regulatory agency and thus not subject to the requirements of E.O. 12866 (58 FR 51735, Sept. 30, 1993).

Executive Order 13132, Federalism

The FLRA is an independent regulatory agency and thus not subject to the requirements of E.O. 13132 (64 FR 43255, Aug. 4, 1999).

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This action is not a major proposed rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act of 1995

The proposed regulations contain no additional information collection or record-keeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

List of Subjects in 5 CFR Parts 2471 and 2472

Administrative practice and procedure, Government employees, Labor management relations.

For the reasons discussed in the preamble, the FLRA proposes to amend 5 CFR parts 2471 and 2472 as follows:

PART 2471—PROCEDURES OF THE PANEL

■ 1. The authority citation for part 2471 continues to read as follows:

Authority: 5 U.S.C. 7119, 7134.

■ 2. Revise § 2471.2 to read as follows:

§ 2471.2 Request form.

A form is available for parties to use in filing either a request for consideration of an impasse or an approval of a binding arbitration procedure. Copies are available on the FLRA's website at www.flra.gov or, with advance permission only, from the Office of the Executive Director, Federal Service Impasses Panel, Suite 300, 1400 K Street NW, Washington, DC 20424-0001. Telephone (771) 444-5762. Use of the form is not required, provided that the request includes all of the information set forth in § 2471.3.

■ 3. Amend § 2471.5 by revising paragraphs (a) introductory text, (a)(1), (b) introductory text, (b)(1), and (d) to read as follows:

§ 2471.5 Filing and Service.

(a) *Filing and service of request.*

(1) Any party submitting a request for Panel consideration of an impasse or a request for approval of a binding arbitration procedure shall file an original and one copy with the Panel, unless the request is filed electronically as discussed below. A clean copy may be submitted for the original. Requests may be submitted electronically through use of the eFiling system on the FLRA's website at www.flra.gov, or by registered mail, certified mail, regular mail, or commercial delivery. Requests also may be accepted by the Panel if transmitted to the facsimile machine of its office, the number of which is (202) 482-6674. A party submitting a request by facsimile shall also file an original for the Panel's records, but failure to do so shall not affect the validity of the filing by facsimile, if otherwise proper. While requests may also be submitted by in-person delivery to the FSIP, you must first obtain permission, by calling (771) 444-5762, and then schedule an appointment at least one business day in advance of submission. In-person delivery is accepted with permission, and by appointment only, Monday through Friday (except federal holidays).

(b) *Filing and service of other documents.*

(1) Any party submitting a response to, or other document in connection with, a request for Panel consideration of an impasse or a request for approval of a binding arbitration procedure shall file an original and one copy with the Panel, with the exception of responses or documents filed simultaneously with the electronic filing of a request through use of the FLRA's eFiling system. Responses or documents may be submitted electronically through use of the eFiling system on the FLRA's

website at www.flra.gov, or by registered mail, certified mail, regular mail, or commercial delivery. Responses or documents also may be accepted by the Panel if transmitted to the facsimile machine of its office, the number of which is (202) 482-6674. A party submitting a response or document by facsimile shall also file an original for the Panel's records, but failure to do so shall not affect the validity of the filing by facsimile, if otherwise proper. While responses or documents may also be submitted by in-person delivery to the FSIP, you must first obtain permission, by calling (771) 444-5762, and then schedule an appointment at least one business day in advance of submission. In-person delivery is accepted with permission, and by appointment only, Monday through Friday (except federal holidays).

(d) The date of service or date served shall be the day when the matter served, if properly addressed, is deposited in the U.S. mail, deposited with a commercial-delivery service that will provide a record showing the date the document was tendered to the delivery service, or delivered in person after permission to do so is granted. Where service is made by electronic or facsimile transmission, the date of service shall be the date of transmission.

PART 2472—IMPASSES ARISING PURSUANT TO AGENCY DETERMINATIONS NOT TO ESTABLISH OR TO TERMINATE FLEXIBLE OR COMPRESSED WORK SCHEDULES

■ 4. The authority citation for part 2472 continues to read as follows:

Authority: 5 U.S.C. 6131.

■ 5. Revise § 2472.3 to read as follows:

§ 2472.3 Request for Panel Consideration.

Either party, or the parties jointly, may request the Panel to resolve an impasse resulting from an agency determination not to establish or to terminate a flexible or compressed work schedule by filing a request as hereinafter provided. A form is available for use by the parties in filing a request with the Panel. Copies are available on the FLRA's website at www.flra.gov or, with advance permission only, from the Office of the Executive Director, Federal Service Impasses Panel, Suite 300, 1400 K Street NW, Washington, DC 20424-0001. Telephone (771) 444-5762. Fax (202) 482-6674. Use of the form is not required provided that the request

includes all of the information set forth in § 2472.4.

■ 6. Revise § 2472.5 to read as follows:

§ 2472.5 Where to file.

Requests to the Panel provided for in this part must either be filed electronically through use of the FLRA's eFiling system on the FLRA's website at www.flra.gov, or be addressed to the Executive Director, Federal Service Impasses Panel, Suite 300, 1400 K Street NW, Washington, DC 20424-0001. All inquiries or correspondence on the status of impasses or other related matters must be submitted by regular mail to the street address above, by using the telephone number (771) 444-5762, or by using the facsimile number (202) 482-6674.

■ 7. Amend § 2472.6 by revising paragraphs (a) introductory text, (a)(1), (b) introductory text, (b)(1), and (d) to read as follows:

§ 2472.6 Filing and service.

(a) *Filing and service of request.*

(1) Any party submitting a request for Panel consideration of an impasse filed pursuant to § 2472.3 of these rules shall file an original and one copy with the Panel unless the request is filed electronically as discussed below. A clean copy may be submitted for the original. Requests may be submitted electronically through use of the eFiling system on the FLRA's website at www.flra.gov, or by registered mail, certified mail, regular mail, or commercial delivery. Requests also may be accepted by the Panel if transmitted to the facsimile machine of its office, the number of which is (202) 482-6674. A party submitting a request by facsimile shall also file an original for the Panel's records, but failure to do so shall not affect the validity of the filing by facsimile, if otherwise proper. While requests may also be submitted by in-person delivery to the FSIP, you must first obtain permission, by calling (771) 444-5762, and then schedule an appointment at least one business day in advance of submission. In-person delivery is accepted with permission, and by appointment only, Monday through Friday (except federal holidays).

(b) *Filing and service of other documents.*

(1) Any party submitting a response to, or other document in connection with, a request for Panel consideration of an impasse filed pursuant to § 2472.3 shall file an original and one copy with the Panel, with the exception of responses or documents that are filed simultaneously with the electronic

filing of a request for Panel consideration. A clean copy may be submitted for the original. Responses or documents may be submitted electronically through use of the eFiling system on the FLRA's website at www.flra.gov, or by registered mail, certified mail, regular mail, or commercial delivery. Responses or documents also may be accepted by the Panel if transmitted to the facsimile machine of its office, the number of which is (202) 482-6674. A party submitting a response or document by facsimile shall also file an original for the Panel's records, but failure to do so shall not affect the validity of the filing by facsimile, if otherwise proper. While responses or documents may also be submitted by in-person delivery to the FSIP, you must first obtain permission, by calling (771) 444-5762, and then schedule an appointment at least one business day in advance of submission. In-person delivery is accepted with permission, and by appointment only, Monday through Friday (except federal holidays).

* * * * *

(d) The date of service or date served shall be the day when the matter served, if properly addressed, is deposited in the U.S. mail, deposited with a commercial-delivery service that will provide a record showing the date the document was tendered to the delivery service, or delivered in person after permission to do so is granted. Where service is made by electronic or facsimile transmission, the date of service shall be the date of transmission.

* * * * *

The Postal Service states that the usual approach of taking "the unit discount from the published benchmark price" divided by the avoided cost "did not work because the benchmark price varies with the different weights of the pieces mailed." *Id.* at 3. The Postal Service states that it could only calculate the workshare discounts for these flat-shaped USPS Marketing Mail mailpieces on a weighted basis after mailing, "when the weights and

¹ Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal One), February 8, 2024 (Petition).

Approved: February 12, 2024.

Thomas Tso,

Solicitor and Federal Register Liaison, Federal Labor Relations Authority.

[FR Doc. 2024-03210 Filed 2-15-24; 8:45 am]

BILLING CODE 7627-01-P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2024-3; Order No. 6965]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is acknowledging a recent filing requesting the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal One). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 26, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

II. Proposal One

III. Notice and Comment

IV. Ordering Paragraphs

I. Introduction

On February 8, 2024, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.¹ The Petition identifies the proposed analytical changes filed in this docket as Proposal One.

II. Proposal One

Background. The Postal Service has in recent years made several proposals to improve the methodology used to calculate dropship workshare discounts for various flat-shaped USPS Marketing Mail mailpieces. Petition, Proposal One at 1. For some flat-shaped USPS Marketing Mail pieces, two rates are available: (1) a per-piece rate for pieces up to a 4-ounce breakpoint weight; (2) and a combined rate, per piece and per pound, for pieces heavier than the 4-ounce breakpoint weight. *Id.* In 2017, the Postal Service's passthrough calculation divided the discount for the heavier pieces by the avoided cost per pound for all pieces, both above and below the 4-ounce breakpoint. *Id.* at 2. The Postal Services states that this method was "incomplete," because "[i]t did not include in its numerator pieces below the pricing breakpoint, but it did include the weight of those pieces in the denominator." *Id.* Therefore, the Postal Service proposed, and the Commission approved, the following methodology to calculate dropship workshare discounts for USPS Marketing Mail that included the discount for pieces at or below the breakpoint weight in the numerator:

$$((\text{Pound discount} * \text{Pounds above breakpoint}) + (\text{Piece discount} * \text{Pieces below breakpoint}))$$

$$(\text{Avoided cost per pound} * \text{Pounds above and below breakpoint})^2$$

numbers of pieces sent were known." *Id.* The Postal Service contends that, as a practical matter, the passthrough percentages for these mailpieces could sometime vary widely with changes in mail volumes and weights which, in turn, made it more difficult for the passthrough percentages to meet the requirements of 39 CFR 3030.284 and 3030.284. *Id.*

The Postal Services states that it identified the problem complying with

39 CFR 3030.284 and 3030.284 in Docket No. R2021-2, "where it was mathematically impossible for the Postal Service to make all six passthrough percentages for Basic Carrier Route Flats (those on 5-Digit pallets and those on all other pallets)" comply with the Commission's workshare discount regulations.³ The Postal Service therefore filed a petition to address the non-compliance by modifying how it calculated and

² *Id.* (citing Docket No. RM2017-11, Order on Analytical Principles Used in Periodic Reporting (Proposal Seven), November 20, 2017, at 4, 8 (Order No. 4227)).

³ *Id.*; see Docket No. R2021-2, Order on Price Adjustments for First-Class Mail, USPS Marketing Mail, Periodicals, Package Services, and Special Services Products and Related Mail Classification Changes, July 19, 2021 (Order No. 5937).

reported passthroughs for USPS Marketing Mail flats.⁴ Specifically, the Postal Service proposed to calculate and report passthroughs for USPS Marketing Mail Carrier Route Flats on 5-digit pallets and passthroughs for all other USPS Marketing Mail Carrier Route Flats together rather than separately. Petition, Proposal One at 4. The Commission approved this proposal and Postal Service notes that the Commission observed that the prior methodology “leads to anomalous results and could precipitate inefficient pricing.”⁵

The Postal Service states that while the adjustments in 2021 prevented the compliance problem for USPS Marketing Mail Carrier Route Flats on 5-digit pallets from reoccurring, “the adjustments did not otherwise change the methodology for calculating passthrough percentages for other flat-shaped [USPS] Marketing Mail pieces with piece and pound price components.” *Id.* at 5. Instead, the Postal Service states that changes in volumes and weight cause compliance issues with 39 CFR 3030.284 and 3030.284. *Id.* The Postal Service states that it “found a great disparity in the volumes and weights of [USPS] Marketing Mail Carrier Route Flats dropshipped at the [destination sectional center facility] DSCF and [destination delivery unit (DDU)].” *Id.* at 5. The Postal Service states that it requested, and the Commission granted, a waiver permitting the passthrough percentage for USPS Marketing Mail Carrier Route Flats dropshipped at the DDU to be 105 percent.⁶ Thereafter, the Postal Service again revised the way it prices flat-shaped USPS Marketing Mail pieces with piece and pound price components and offering dropship discounts on per-piece prices only, which the Commission approved.⁷

⁴ Petition, Proposal One at 3; see Docket No. RM2021–6, Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), April 8, 2021.

⁵ Petition, Proposal One at 4–5 (citing Docket No. RM2021–6, Order on Analytical Principles Used in Periodic Reporting (Proposal Three), November 4, 2021, at 11 (Order No. 6032)). Additionally, the Postal Service states that, in approving the price adjustments in Docket No. R2021–2, the Commission also granted a one-time exemption from 39 CFR part 3030, subpart J for Basic Carrier Route Flats entered at the [Destination Delivery Unit] DDU workshare discount that noted the “mathematical impossibility” of compliance. Petition, Proposal One at 4.

⁶ *Id.* at 5–6 (citing Docket No. RM2022–12, Order Approving Postal Service Application for Waiver under 39 CFR 3030.286, August 30, 2022, at 9, 11 (Order No. 6261)).

⁷ Petition, Proposal One at 6, 7–8 (citing Docket No. RM2023–4, Petition of the United States Postal Service for the Initiation of a Proceeding to

The Postal Service’s current methodology for calculating workshare discount passthrough percentages is “the same . . . as it uses for most other products, dividing the per-piece discount by the per-piece cost avoidance.” Petition, Proposal One at 7. The Postal Service states that the passthrough percentages no longer vary with the different weights of pieces mailed because the passthroughs are calculated independently of the volumes and weights of pieces mailed. *Id.*

The Postal Service states that its current methodology for calculating workshare discount passthrough percentages “has some limitations.” *Id.* The Postal Service argues that because pound prices do not vary by dropship entry point, it reduces incentives for mailers to dropship flat-shaped pieces weighing more than 4 ounces closer to their delivery destinations. *Id.* at 8. The Postal Service also states that its current methodology does not “reflect the avoided costs of delivering flat-shaped [USPS] Marketing Mail pieces as closely as they could.” *Id.* at 9. Instead, the Postal Service states that workshare discounts for pieces weighing more than 4 ounces are too small relative to their avoided costs, while those for pieces weighing 4 ounces or less are too large. *Id.*

Proposal. The Postal Service proposes to address the limitations in its current methodology for calculating workshare discount passthrough percentages by separately deriving prices for flat-shaped USPS Marketing Mail pieces at or below the 4-ounce breakpoint from those pieces above the 4-ounce breakpoint. *Id.* For mailpieces at or below the 4-ounce breakpoint, the Postal Service states that:

- mailers would continue to pay only a per-piece price;
- dropship discounts would be given on these per-piece prices, so that per-piece prices would still vary based upon entry (*i.e.*, origin, (destination network distribution center) DNDC, DSCF, or DDU); and
- the methodology for calculating passthroughs would remain substantially unchanged from the current formula.

Id. at 10. The Postal Service states that the only difference in its proposed methodology and the current methodology is the per-piece cost avoidance from Folder 13, as submitted in its annual compliance filing. *Id.* The

Consider Proposed Changes in Analytical Principles (Proposal One), February 10, 2023; Docket No. RM2023–4, Order on Analytical Principles Used in Periodic Reporting (Proposal One), April 6, 2023, at 14 (Order No. 6474).

Postal Service’s proposed methodology for calculating workshare discount passthrough percentages for these pieces is as follows:

Per-piece dropship discount/per-piece dropship cost avoidance of lightweight pieces (Folder 13)

Id. The Postal Service contends that the change to the cost avoidance component of the passthrough calculation is much closer to actual avoided costs than if the weights of pieces over 4-ounces were included. *Id.*

For mailpieces weighting 4-ounces or more, the Postal Service states:

- prices would continue to have per-piece and per-pound components;
- pound prices would, once again, apply to the entire weight of a piece, not just the pounds above the breakpoint as they do in the current price structure; and

• the Postal Service would reintroduce per-pound dropship discounts, and so the per-pound prices would again vary by dropship entry point, as they did prior to adopting the current methodology.

Id. at 10–11. The Postal Service states that, instead of basing dropship discounts on the per-piece rates and cost avoidances, it proposes to base dropship workshare discounts for pieces weighing 4 ounces or more on the per-pound component of the rates. *Id.* at 12. As such, the Postal Service’s proposed methodology for calculating passthroughs for pieces weighing 4 ounces or more is:

Per-pound dropship discount/Per-pound dropship cost avoidance (Folder 13)

Id.

The Postal Service contends that “the virtue” of the proposed methodology is that the discounts are tied directly to the per-pound cost avoidance and are “better aligned with actual cost avoidances” because they are “based on actual weight.” *Id.* at 12. Finally, the Postal Service argues that an “immediate effect” of its proposal would be to double the number of workshare discounts, from eight discounts to 16, for dropshipped flat-shaped USPS Marketing Mail mailpieces. *Id.* at 12–13.

III. Notice and Comment

The Commission establishes Docket No. RM2024–3 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission’s website at <http://www.prc.gov>. Interested persons may submit comments on the Petition and Proposal One no later than February 26, 2024. Pursuant to 39 U.S.C.

505, JP Klingenberg is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2024–3 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal One), filed February 8, 2024.

2. Comments by interested persons in this proceeding are due no later than February 26, 2024.

3. Pursuant to 39 U.S.C. 505, the Commission appoints JP Klingenberg to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,
Secretary.

[FR Doc. 2024–03270 Filed 2–15–24; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2024–0064; FRL–11722–01–R7]

Air Plan Approval; Iowa; State Implementation Plan and State Operating Permits Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Iowa State Implementation Plan (SIP) and the Operating Permit Program for the State of Iowa. The revisions update incorporations by reference to EPA methods for performance testing (stack testing), update the definitions, and adopt the most recent National Ambient Air Quality Standards (NAAQS) for ozone. These revisions do not impact the stringency of the SIP or have an adverse effect on air quality. The EPA's proposed approval of this rule revision is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments must be received on or before March 18, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2024–0064 to <https://www.regulations.gov>. Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will 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 “Written Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Bethany Olson, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7905; email address: olson.bethany@epa.gov.

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

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- I. Written Comments
- II. What is being addressed in this document?
- III. What SIP revisions are being proposed by EPA?
- IV. What operating permit plan revisions are being proposed by EPA?
- V. Have the requirements for approval of a SIP and the operating permit plan revisions been met?
- VI. What action is the EPA taking?
- VII. Incorporation by Reference
- VIII. Statutory and Executive Order Reviews

I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2024–0064, at <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically 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. 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>.

II. What is being addressed in this document?

The EPA is proposing to approve revisions to the Iowa SIP and the Operating Permits Program received on March 29, 2023. The revisions incorporate recent changes to Iowa Administrative Code. The following chapters are impacted:

- Chapter 20, “Scope of Title—Definitions;”
- Chapter 22, “Controlling Pollution;”
- Chapter 25, “Measurement of Emissions;” and
- Chapter 28, “Ambient Air Quality Standards.”

The revisions update incorporations by reference to EPA methods for performance testing (stack testing) and adopt the most recent National Ambient Air Quality Standards (NAAQS) for ozone. EPA proposes to find that these revisions meet the requirements of the Clean Air Act, do not impact the stringency of the SIP, and do not adversely impact air quality. The full text of these changes can be found in the State's submission, which is included in the docket for this action.

Sections 111 and 112 of the Clean Air Act (CAA) allow EPA to delegate authority to states for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPs). EPA has delegated authority to Iowa for approved portions of these sections of the CAA. Changes made to Iowa's Chapter 23 pertaining to new and revised NSPS and NESHAPs are not directly approved into the SIP, but rather, are adopted by reference. Thus, EPA is not proposing to approve the changes to Chapter 23 of the Iowa Administrative Code into the state's SIP.

III. What SIP revisions are being proposed by EPA?

The EPA is proposing the following revisions to the Iowa SIP:

Chapter 20, Subrule 20.2, Scope of Title-Definitions: The state revised the definition of “EPA reference method” to adopt the most current performance test (stack test) method as specified in 40 CFR part 60, appendix A and amended or corrected through February 16, 2021. The proposed update will ensure that state reference methods are equivalent to Federal reference methods; thus, EPA proposes to approve this change.

Chapter 25, Subrule 25.1(9), Testing and Sampling of New and Existing Equipment: As discussed above, the State similarly revised subrule 25.1(9), “Methods and Procedures,” to adopt the performance test (stack test) methods as specified in 40 CFR part 60, appendix A and amended or corrected through February 16, 2021. The proposed update will ensure that state reference methods are equivalent to Federal reference methods; thus, EPA proposes to approve this change.

Chapter 28, Subrule 28.1, State-wide Standards: The state revised subrule 28.1, to adopt the most current national primary and secondary ambient air quality standards for ozone as specified in 40 CFR part 50 and amended at 80 FR 65291–65468 (October 26, 2015).

IV. What operating permit plan revisions are being proposed by EPA?

The EPA is proposing to approve the following revision to the Operating Permit Program:

Chapter 22, subrule 22.100(455B), Definitions for Title V Operating Permits: The state revised the definition of “EPA reference method” to adopt the most current performance test (stack test) method as specified in 40 CFR part 60, appendix A and amended or corrected through February 16, 2021. The state also revised the definition of “Hazardous air pollutant” to add the chemical 1-bromopropane, CAS#106–94–5, to the list of hazardous air pollutants. This revision is consistent with the most current list of hazardous air pollutants at 40 CFR part 63, subpart C. The proposed updates will ensure consistency between federal and state regulations; thus, EPA proposes to approve this change.

V. Have the requirements for approval of a SIP and the operating permit plan revisions been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from November 22, 2022, to December 5, 2022, and held a public hearing on December 5, 2022. The State received no comments. In addition, as explained above, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

VI. What action is the EPA taking?

We are processing this as a proposed action because we are soliciting comments on this proposed action.

Final rulemaking will occur after consideration of any comments.

VII. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Iowa rules 567–20.2, Definitions, which provides definitions for air quality regulations; 567–25.1, Testing and Sampling of New and Existing Equipment, which regulates testing and sampling of equipment; 567–28.1, State-wide Standards, which regulates ambient air quality standards; and 22.100, Definitions for Title V Operating Permits, which provides definitions for state operating permits. The state effective date of these rules is March 15, 2023. The EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VIII. 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 Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address “disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. 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.” EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

The Iowa Department of Natural Resources did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no

information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects

40 CFR Part 52

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

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: February 12, 2024.

Meghan A. McCollister,
Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR parts 52 and 70 as set forth below:

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 Q—Iowa

■ 2. In § 52.820, the table in paragraph (c) is amended by revising the entries “567–20.2,” “567–25.1,” and “567–28.1” to read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED IOWA REGULATIONS

Iowa citation	Title	State effective date	EPA approval date	Explanation
Iowa Department of Natural Resources Environmental Protection Commission [567]				
Chapter 20—Scope of Title-Definitions				
567–20.2	Definitions	3/15/2022	[Date of publication of the final rule in the Federal Register], [Federal Register citation of the final rule].	The definitions for “anaerobic lagoon,” “odor,” “odorous substance,” “odorous substance source” are not SIP approved.
* * *	* * *	* * *	* * *	* * *
Chapter 25—Measurement of Emissions				
567–25.1	Testing and Sampling of New and Existing Equipment.	3/15/2023	[Date of publication of the final rule in the Federal Register], [Federal Register citation of the final rule].	
* * *	* * *	* * *	* * *	* * *
Chapter 28—Ambient Air Quality Standards				
567–28.1	Statewide standards	3/15/2023	[Date of publication of the final rule in the Federal Register], [Federal Register citation of the final rule].	
* * *	* * *	* * *	* * *	* * *

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PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. Appendix A to part 70 is amended by adding paragraph (z) under “Iowa” to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Iowa

* * * * *

(z) The Iowa Department of Natural Resources submitted for program approval revisions to rule 567–22.100 on March 29, 2023. The state effective date is March 15, 2023. The proposed revision effective date is [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

* * * * *

[FR Doc. 2024–03295 Filed 2–15–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2023–0470; EPA–HQ–OLEM–2023–0471; EPA–HQ–OLEM–2023–0571; EPA–HQ–OLEM–2023–0594; EPA–HQ–OLEM–2024–0014; FRL–11693–01–OLEM]

Proposed Deletion From the National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a Notice of Intent to delete one site and partially delete four sites from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the states, through their designated state agency, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments regarding this proposed action must be submitted on or before March 18, 2024.

ADDRESSES: EPA has established a docket for this action under the Docket Identification numbers included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. Submit your comments, identified by the appropriate Docket ID number, by one of the following methods:

- <https://www.regulations.gov>.

Follow on-line instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically 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. 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 <http://www2.epa.gov/dockets/commenting-epa-dockets>.

- *Email:* Table 2 in the

SUPPLEMENTARY INFORMATION section of this document provides an email address to submit public comments for the proposed deletion action.

Instructions: Direct your comments to the Docket Identification number included in Table 1 in the

SUPPLEMENTARY INFORMATION section of

this document. 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <https://www.regulations.gov> or email. The <https://www.regulations.gov> website is an "anonymous access" system, which means 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 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under the Docket Identification included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. All documents in the docket are listed on the <https://www.regulations.gov> website. The Final Close-Out Report (FCOR, for a full site deletion) or the Partial Deletion Justification (PDJ, for a partial site deletion) is the primary document which summarizes site information to support the deletion. It is typically written for a broad, non-technical audience and this document is included in the deletion docket for each of the sites in this rulemaking. Although listed in the index, some information is not publicly available, *i.e.*, 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. Docket materials are available through <https://www.regulations.gov> or at the corresponding Regional Records Center. Location, address, and phone

number of the Regional Records Centers follows.

Regional Records Center:

- Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; 212/637–4308.
- Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street SW, Mail code 9T25, Atlanta, GA 30303.
- Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Records Manager, Mail code SRC–7J, Metcalfe Federal Building, 7th Floor South, 77 West Jackson Boulevard, Chicago, IL 60604, 312/886–4465.
- Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mail code Records Center, Denver, CO 80202–1129; 303/312–7273.
- EPA Headquarters Docket Center Reading Room (deletion dockets for all states), William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004, 202/566–1744.

EPA staff listed below in the **FOR FURTHER INFORMATION CONTACT** section may assist the public in answering inquiries about deleted sites, accessing deletion support documentation, and determining whether there are additional physical deletion dockets available.

FOR FURTHER INFORMATION CONTACT:

- Mabel Garcia, U.S. EPA Region 2 (NJ, NY, PR, VI), garcia.mabel@epa.gov, 212/637–4356.
- Leigh Lattimore, U.S. EPA Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), lattimore.leigh@epa.gov, 404/562–8768.
- Karen Cibulskis, U.S. EPA Region 5 (IL, IN, MI, MN, OH, WI), cibulskis.karen@epa.gov, 312/886–1843.
- Linda Kiefer, U.S. EPA Region 8 (CO, MT, ND, SD, UT, WY), kiefer.linda@epa.gov, 303/312–6689.
- Charles Sands, U.S. EPA Headquarters, sands.charles@epa.gov, 202/566–1142.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. NPL Deletion Criteria
- III. Deletion Procedures
- IV. Basis for Intended Full Site or Partial Site Deletion

I. Introduction

EPA is issuing a proposed rule to delete one site and partially delete four sites from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the NCP, which EPA created under section 105 of the CERCLA statute of 1980, as amended. EPA maintains the NPL as those sites

that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). These partial deletions are proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466, (November 1, 1995). As described in 40 CFR 300.425(e)(3) of the NCP, a site or portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

EPA will accept comments on the proposal to delete or partially delete these sites for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III of this document discusses procedures that EPA is using for this action. Section IV of this document discusses the site or portion of the site proposed for deletion and demonstrates how it meets the deletion criteria, including reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

- i. Responsible parties or other persons have implemented all appropriate response actions required;
- ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or
- iii. The remedial investigation has shown that the release poses no

significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to the deletion or partial deletion of the sites in this proposed rule:

(1) EPA consulted with the respective state before developing this Notice of Intent for deletion.

(2) EPA has provided the state 30 working days for review of site deletion documents prior to publication of it today.

(3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate.

(4) The state, through their designated state agency, has concurred with the proposed deletion action.

(5) Concurrently, with the publication of this Notice of Intent for deletion in the **Federal Register**, a notice is being published in a major local newspaper of general circulation near the site. The newspaper announces the 30-day public comment period concerning the proposed action for deletion.

(6) The EPA placed copies of documents supporting the proposed deletion in the deletion docket, made these items available for public inspection, and copying at the Regional Records Center identified above.

If comments are received within the 30-day comment period on this document, EPA will evaluate and

respond accordingly to the comments before making a final decision to delete or partially delete the site. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete or partially delete the site, the EPA will publish a final Notice of Deletion or Partial Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and included in the site information repositories listed above.

Deletion of a site or a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site or a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Full Site or Partial Site Deletion

The site to be deleted or partially deleted from the NPL, the location of the site, and docket number with information including reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete are specified in Table 1. The NCP permits activities to occur at a deleted site, or that media or parcel of a partially deleted site, including operation and maintenance of the remedy, monitoring, and five-year reviews. These activities for the site are entered in Table 1, if applicable, under Footnote such that; 1 = site has continued operation and maintenance of the remedy, 2 = site receives continued monitoring, and 3 = site five-year reviews are conducted.

TABLE 1

Site name	City/county, state	Type	Docket No.	Footnote
Allied Paper, Inc./Portage Ck/Kalamazoo River	Kalamazoo, MI	Partial	EPA-HQ-OLEM-2023-0470	1, 2, 3
South Minneapolis Residential Soil Contamination	Minneapolis, MN	Partial	EPA-HQ-OLEM-2023-0471	
Libby Asbestos	Libby, MT	Partial	EPA-HQ-OLEM-2023-0571	1, 3
Lipari Landfill	Pitman, NJ	Full	EPA-HQ-OLEM-2023-0594	1, 2, 3
Sapp Battery Salvage	Cottdonale, FL	Partial	EPA-HQ-OLEM-2024-0014	1, 3

Table 2 includes information concerning whether the full site is proposed for deletion from the NPL or a description of the area, media or

Operable Units (OUs) of the NPL site proposed for partial deletion from the NPL, and an email address to which public comments may be submitted if

the commenter does not comment using <https://www.regulations.gov>.

TABLE 2

Site name	Full site deletion (full) or media/parcels/description for partial deletion	E-mail address for public comments
Allied Paper, Inc./Portage Ck/Kalamazoo River	A portion of land/soil from OU 2, the Area East of Davis Creek and the Non-Easement Portion of the Area East of Davis Creek Extension Area of the Willow Boulevard/A-Site (WB/A-Site).	Cibulskis.karen@epa.gov .
South Minneapolis Residential Soil Contamination	Three residential properties	Cibulskis.karen@epa.gov .
Libby Asbestos	400-acre industrial park (OU-5)	Zinner.dania@epa.gov .
Lipari Landfill	Full	Mitchell.tanya@epa.gov .
Sapp Battery Salvage	Soils, sediments and surface water portions of OU 1 and OU 3.	Spalvins.erik@epa.gov .

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1251 *et seq.*; 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Larry Douchand,

Office Director, Office of Superfund Remediation and Technology Innovation.

[FR Doc. 2024–03004 Filed 2–15–24; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Part 102–118

[FMR Case 2023–02; Docket No. GSA–FMR–2023–0014; Sequence No. 1]

RIN 3090–AK73

Federal Management Regulation; Transportation Payment and Audit Regulations

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The United States General Services Administration (GSA) proposes to amend the Federal Management Regulation (FMR) to effectuate fundamental changes including removing, adding, and modifying definitions, eliminating gender pronouns, streamlining requirements, and revising statutory references. These changes are needed to provide accurate information for agencies to properly manage and comply with transportation invoice payment and audit requirements.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before April 16, 2024 to be considered in the formation of the proposed rule.

ADDRESSES: Submit comments in response to FMR Case 2023–02 to [Regulations.gov](https://www.regulations.gov) at <https://www.regulations.gov> via the Federal eRulemaking portal by searching for “FMR Case 2023–02”. Select the link “Comment Now” that corresponds with FMR Case 2023–02. Follow the instructions provided at the “Comment Now” screen. Please include your name, company name (if any), and “FMR Case

2023–02” 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 FMR Case 2023–02, 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. Ron Siegel, Policy Analyst, at 202–702–0840 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 FMR Case 2023–02.

SUPPLEMENTARY INFORMATION:

I. Background

The Travel and Transportation Reform Act of 1998 (Pub. L. 105–264) established the statutory requirement for agencies to perform an audit of transportation expenses prior to payment, granted the Administrator of GSA the authority to prescribe regulations for the audit of transportation invoices prior to payment, and the statutory authority for audit oversight to protect the financial interests of the Government (31 U.S.C. 3726). GSA has codified these requirements in 41 CFR 102–118, Transportation Payment and Audit (Federal Management Regulation (FMR) part 102–118).

GSA last amended FMR part 102–118 on May 31, 2022 (87 FR 32320), to perform editorial and technical changes.

That direct final rule introduced the GSA Transportation Audit Management System (TAMS), corrected inaccurate and outdated information, and removed obsolete references to programs, legal citations, and forms. It revised general contact information, corrected hyperlinks, clarified conditions for using certain forms and revised outdated and inaccurate administrative procedures.

GSA is proposing amendments to FMR part 102–118. These amendments include modifying definitions that apply to this part, which include the incorporation of previously undefined terms such as Civilian Board of Contract Appeals (CBCA), refund, and Transportation Audits Management System (TAMS). Furthermore, definitions of forms used exclusively by the GSA Transportation Audits Division will be removed from individual sections and added to the definitions, while terms such as EDI signature, reparation, statement of difference rebuttal, and virtual Government Bill of Lading (GBL), which are defined but not referenced in this part, will be removed. Additionally, certain definitions will be modified to enhance clarity, including for the terms cash, Government contractor issued charge card, and offset. This proposed rule will standardize the terminology used to reference Government contractor issued charge cards and will include definitions for the two types of charge cards that the Government may use to procure transportation: individually billed travel cards and agency purchase cards.

This proposed rule provides further clarification on the role of TAMS and its benefit to transportation service providers (TSPs), specifically when filing certain claims. It also outlines the circumstances under which Federal agencies use TAMS. Additionally, when agencies submit their paid transportation invoices and other documentation through TAMS, it allows the GSA Transportation Audits Division to maintain and store these transportation records in accordance with the General Records Schedule.

Thanks to the convenience of email and the efficiency of TAMS, GSA no longer requires physical documents to be sent via the United States Postal Service mail monthly. Consequently, physical mailing addresses are being removed from this FMR part. This change is expected to reduce costs for agencies, streamline the reporting process, and eliminate the need for mailing documents to the GSA Transportation Audits Division. It will also simplify the claims filing process

for TSPs that want to file a claim with the GSA Transportation Audits Division.

GSA is proposing to grant agencies some discretion in the use of a GBL for domestic shipping. Currently, the regulation restricts GBL usage to international or domestic overseas shipments. The changes outlined in this rulemaking would permit agencies to execute a GBL when the agency considers it necessary. Furthermore, this rulemaking clarifies that a bill of lading can be utilized to procure both transportation and transportation services.

This proposed rule builds upon the changes introduced in the direct final rule that was published on May 31, 2022 at 87 FR 32320. That rule eliminated unnecessary procedures for agencies to request Government Bill of Lading (GBL) and Government Transportation Request (GTR) forms, along with their corresponding control numbers. GSA is proposing amendments to this FMR part that will provide agencies with additional information regarding the requirement to assign numbers to these forms and to manage and track each issued GBL and GTR transportation document.

This proposed rule updates the requirement for agencies to provide a copy of each quotation, tender, or contract of special rates, fares, charges, or concessions with TSPs to the GSA Transportation Audits Division. The proposed revision adds the requirement for agencies to send copies of rates provided by pipeline carriers as well. Furthermore, this rulemaking clarifies that the Director of the GSA Transportation Audits Division has the authority to conduct postpayment audits on any agency paid transportation invoice, oversee agency prepayment audit programs, settle accounts, and initiate collection activities.

Finally, GSA is also updating information, including correcting legal references related to actions by and against the Government. The revised information corrects authorities that apply to time limits for filing freight charges, loss and damage claims, and filing claims against a TSP for the collection of overcharges. It is also important to note that this proposed rule would also remove gender pronouns from this FMR part.

II. Executive Orders 12866, 13563, and 14094

Executive Order (E.O.) 12866 (Regulatory Planning and Review) directs 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 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. E.O. 14094 (Modernizing Regulatory Review) amends section 3(f) of Executive Order 12866 and supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in E.O. 12866 and E.O. 13563. The Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) has determined that this rulemaking is not a significant regulatory action and, therefore, it is not subject to review under section 6(b) of E.O. 12866.

III. Regulatory Flexibility Act

GSA does not expect this proposed 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.* This proposed rule is also exempt from the Administrative Procedure Act pursuant to 5 U.S.C. 553(a)(2) because it applies to agency management or personnel. Therefore, an Initial Regulatory Flexibility Analysis has not been performed.

IV. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FMR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that requires the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

List of Subjects in 41 CFR Part 102–118

Accounting, Claims, Government property management, Reporting and recordkeeping requirements, Transportation.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

Therefore, GSA proposes to amend 41 CFR part 102–118 as set forth below:

PART 102–118—TRANSPORTATION PAYMENT AND AUDIT

■ 1. The authority citation for 41 CFR part 102–118 continues to read as follows:

Authority: 31 U.S.C. 3726; 40 U.S.C. 121(c); 40 U.S.C. 501, *et seq.*; 46 U.S.C. 55305; 49 U.S.C. 40118.

§ 102–118.25 [Amended]

- 2. Amend § 102–118.25 by removing the words “may request” and adding the words “is required” in their place.
- 3. Amend § 102–118.35 by:
 - a. Adding, in alphabetical order, the definitions “ACH (automated clearinghouse)” and “Agency purchase card”;
 - b. Revising the definition of “Cash”;
 - c. Adding, in alphabetical order, the definitions of “Certificate of Settlement” and “Civilian Board of Contract Appeals (CBCA)”;
 - d. Removing the definition of “EDI signature”;
 - e. Revising the definition of “Government contractor issued charge card”;
 - f. Adding, in alphabetical order, the definitions of “Individually billed travel card”, “Notice of Indebtedness”, and “Notice of Overcharge”;
 - g. Revising the definition of “Offset”;
 - h. Adding the definition of “Refund”;
 - i. Removing the definition of “Reparation”;
 - j. Revising the definition of “Statement of difference”;
 - k. Removing the definition of “Statement of difference rebuttal”;
 - l. Adding the definition of “Transportation Audits Management System (TAMS)”;
 - m. Removing the definition of “Virtual GBL (VGBL)”.

The additions and revisions read as follows:

§ 102–118.35 What definitions apply to this part?

* * * * *

ACH (automated clearinghouse) means a nationwide network through which depository institutions send each other batches of electronic credit and debit transfers.

* * * * *

Agency purchase card means a charge card used by an authorized agency purchaser to procure, order, and pay for supplies and services.

* * * * *

Cash means cash, personal checks, personal charge/credit cards, and traveler’s checks.

Certificate of Settlement means a formal notice to an agency that provides a complete explanation of any amount that is disallowed. GSA produces and transmits the Certificate of Settlement (GSA Form 7931) to the agency whose funds are to be charged for processing and payment.

Civilian Board of Contract Appeals (CBCA) means an independent court

within GSA that settles transportation payment claims disputes between Federal agencies and transportation service providers (TSPs). For additional information on the CBCA see <https://www.cbca.gov/index.html>.

* * * * *

Government contractor issued charge card means an individually billed travel card or an agency purchase card.

* * * * *

Individually billed travel card means the charge card used by authorized individuals to pay for official travel and transportation related expenses for which the contractor bills the employee. This is different from a centrally billed account paying for official travel and transportation related expenses for which the agency is billed.

Notice of Indebtedness means a formal notice issued to a TSP that owes an ordinary debt to an agency. This notice states the basis for the debt, the TSP’s rights, interest, penalty, and other results of nonpayment. The debt is due immediately and is subject to interest charges, penalties, and administrative cost under 31 U.S.C. 3717.

Notice of Overcharge means a formal notice to a TSP that owes a debt to the agency. It shows the TSP the amount paid and the basis for the proper charge for the document reference number (DRN), and cites applicable contract, tariff, or tender, along with other data relied on to support the overcharge.

Offset means withholding money from a payment. In this part, money withheld refers to the funds owed a TSP that are not released by the agency but instead used to repay the Government for a debt incurred by the TSP.

* * * * *

Refund means the amount collected from outside sources for payments made in error, overpayment, or adjustments for previous amounts disbursed.

* * * * *

Statement of difference means a statement issued by an agency or its designated audit contractor during a prepayment audit when it has been determined that a TSP has billed the agency for more than the proper amount for the services. This statement tells the TSP the amount allowed and the basis for the proper charges. The statement also cites the applicable rate references and other data relied on for support. The agency issues a separate statement of difference for each transportation transaction. This can be an electronic process.

* * * * *

Transportation Audits Management System (TAMS) means the GSA’s cloud-based postpaid transportation invoice

auditing solution for Federal agencies and TSPs.

* * * * *

§ 102–118.40 [Amended]

- 4. Amend § 102–118.40 by:
 - a. In paragraph (a), removing the words “Government contractor-issued charge card, purchase order (or electronic equivalent), or a Government bill of lading for international shipments (including domestic overseas shipments)” and adding the words “Government contractor issued charge card, purchase order (or electronic equivalent), or a bill of lading including a Government bill of lading” in their place; and
 - b. In paragraph (b), removing the words “Government issued charge card (or centrally billed travel account citation), Government issued individual travel charge card, personal charge card,” and adding the words “Government contractor issued charge card, centrally billed travel account, personal charge/credit card,” in their place.

§ 102–118.45 [Amended]

- 5. Amend § 102–118.45 by:
 - a. In paragraph (a)(1)(i), removing the words “Government issued agency charge card” and adding the words “Government contractor issued charge card” in their place;
 - b. In paragraph (a)(3)(i), removing the words “Contractor issued individual travel charge card” and adding the words “Government contractor issued charge card (individually billed travel card)” in their place; and
 - c. In paragraph (a)(3)(ii), removing the words “Personal charge card” and adding the words “Personal charge/credit card” in their place.

§ 102–118.50 [Amended]

- 6. Amend § 102–118.50 by:
 - a. In paragraph (a), removing the citation “(31 U.S.C. 3332, et)” and adding the citation “(31 U.S.C. 3332, *et seq.*)” in its place; and
 - b. In paragraph (c), removing the citation “(31 CFR part 208)” and adding the citation “31 CFR part 208” in its place.
- 7. Revise § 102–118.75 to read as follows:

§ 102–118.75 What if my agency or the TSP does not have an account with a financial institution or approved payment agent?

Under 31 U.S.C. 3332, *et seq.*, your agency must obtain an account with a financial institution or approved payment agent in order to meet the statutory requirements to make all Federal payments via EFT unless your

agency receives a waiver from the Department of the Treasury. To obtain a waiver, your agency must contact the Secretary of the Treasury. For information visit: <https://www.fiscal.treasury.gov/>

■ 8. Amend § 102–118.80 by revising the third sentence to read as follows:

§ 102–118.80 Who is responsible for keeping my agency's electronic commerce transportation billing records?

* * * Therefore, your agency must utilize the Transportation Audits Management System (TAMS) (<https://tams.gsa.gov>) to submit all relevant electronic transportation billing documents or submit via email to: QMCATariffs@gsa.gov.

■ 9. Revise § 102–118.115 to read as follows:

§ 102–118.115 Must my agency use a GBL?

No. Your agency is required to use commercial payment practices to the maximum extent possible. Your agency may use a GBL as needed for domestic shipments and should use a GBL for international shipments. When used for shipments, a GBL is a receipt of goods, evidence of title, and a contract of carriage for Government shipments and was developed to protect the interest of the U.S. Government.

§ 102–118.130 [Amended]

■ 10. Amend § 102–118.130 by removing the last sentence.

§ 102–118.150 [Amended]

■ 11. Amend § 102–118.150 by, in paragraph (a), removing the last sentence.

■ 12. Revise § 102–118.235 to read as follows:

§ 102–118.235 Must my agency keep physical control and accountability of the GBL and GTR forms or GBL and GTR numbers?

Yes, your agency is responsible for the physical control, use, and accountability of GBLs and GTRs and must have procedures in place to track, manage,

and account for these documents when necessary.

■ 13. Revise § 102–118.255 to read as follows:

§ 102–118.255 Are GBL and GTR forms numbered and used sequentially?

Yes, GBLs and GTRs must be sequentially numbered by agencies when used.

§ 102–118.260 Must my agency send all quotations, tenders, or contracts with a TSP to GSA?

■ 14. Amend § 102–118.260 by revising paragraph (a) to read as follows:

(a) Yes, your agency must send a copy of each quotation, tender, or contract of special rates, fares, charges, or concessions with TSPs including those authorized by 49 U.S.C. 10721, 13712, and 15504 upon execution to qmcatariffs@gsa.gov.

* * * * *

■ 15. Amend § 102–118.285 by:

- a. Revising paragraph (e);
- b. Removing paragraph (f); and
- c. Redesignating paragraphs (g) through (m) as paragraphs (f) through (l), respectively.

The revisions read as follows:

§ 102–118.285 What must be included in an agency's transportation prepayment audit program?

* * * * *

(e) Agencies must use GSA Transportation Audits Division's electronic commerce system, TAMS, to fulfill all monthly reporting requirements. Filing all documents through TAMS ensures that GSA Transportation Audits Division will properly maintain and store transportation records, including paid transportation bills, in accordance with the General Records Schedule 1.1 *et seq.*, (36 CFR chapter XII, part 1220). GSA will also arrange for storage of any document requiring special handling, such as bankruptcy and court cases. These bills will be retained pursuant to 44 U.S.C. 3309 until claims have been settled.

* * * * *

§ 102–118.300 [Amended]

■ 16. Amend § 102–118.300 by, in paragraph (a), removing the words “by email at Audit.Policy@gsa.gov, or by mail to: U.S. General Services Administration, 1800 F St. NW, 3rd Floor, Mail Hub 3400, Washington, DC 20405.” and adding the words “via TAMS (<https://tams.gsa.gov>), or by email to Audit.Policy@gsa.gov.” in their place.

■ 17. Amend § 102–118.425 by revising paragraph (a) to read as follows:

§ 102–118.425 Is my agency required to forward all transportation documents (TDs) to GSA Transportation Audits Division, and what information must be on these documents?

(a) Yes, your agency must provide all TDs, via TAMS, to GSA Transportation Audits Division (see § 102–118.35 for the definition of TD).

* * * * *

§ 102–118.430 [Amended]

■ 18. Amend § 102–118.430 by:

- a. In paragraph (f), removing the second sentence; and
- b. In paragraph (g), removing the second and third sentences.

§ 102–118.435 [Amended]

■ 19. Amend § 102–118.435 by, in paragraph (a)(7), removing the words “freight or passenger” and adding the word “all” in their place.

§ 102–118.440 [Amended]

■ 20. Amend § 102–118.440 by, in the second sentence, removing the word “type” and adding the word “types” in its place.

■ 21. Revise § 102–118.455 to read as follows:

§ 102–118.455 What is the time limit for a TSP to file a transportation claim against my agency?

The time limits on a TSP transportation claim against the Government differ by mode as shown in the following table:

TIME LIMITS ON ACTIONS TAKEN BY TSP

Mode	Freight charges (years)	Statute
(a) Air Domestic	6	28 U.S.C. 2401, 2501.
(b) Air International	6	28 U.S.C. 2401, 2501.
(c) Freight Forwarders (Subject to title 49 chapter 135)	3	49 U.S.C. 14705(f).
(d) Motor	3	49 U.S.C. 14705(f).
(e) Rail	3	49 U.S.C. 11705(f).
(f) Water (Subject to title 49 chapter 135)	3	49 U.S.C. 14705(f).
(g) Water (Not subject to title 49 chapter 135)	2	46 U.S.C. 30905.
(h) TSPs not specified in any of the above categories	6	28 U.S.C. 2401, 2501.

■ 22. Revise § 102–118.460 to read as follows:

§ 102–118.460 What is the time limit for my agency to file a court claim with a TSP for freight charges, refund of overpayment, and loss or damage to the property?

Statutory time limits vary depending on the mode and the service involved

and may involve freight charges. The following tables list the time limits:

(a) TIME LIMITS ON ACTIONS TAKEN BY THE FEDERAL GOVERNMENT AGAINST TSPs

Mode	Freight charges	Refund for overpayment	Loss and damage
(1) Rail	3 years; 49 U.S.C. 11705	3 years; 49 U.S.C. 11705	6 years; 28 U.S.C. 2415.
(2) Motor	3 years; 49 U.S.C. 14705(f).	3 years; 49 U.S.C. 14705(f).	6 years; 28 U.S.C. 2415.
(3) Freight Forwarders (Subject to title 49 chapter 135)	3 years; 49 U.S.C. 14705(f).	3 years; 49 U.S.C. 14705(f).	6 years; 28 U.S.C. 2415.
(4) Water (Subject to title 49 chapter 135)	3 years; 49 U.S.C. 14705(f).	3 years; 49 U.S.C. 14705(f).	6 years; 28 U.S.C. 2415.
(5) Water (Not subject to title 49 chapter 135)	6 years; 28 U.S.C. 2415 ...	3 years; 46 U.S.C. 41301	3 days after delivery; Carriage of Goods By Sea Act, 46 U.S.C. 30701 Notes.
(6) Domestic Air	6 years; 28 U.S.C. 2415 ...	6 years; 28 U.S.C. 2415 ...	6 years; 28 U.S.C. 2415.
(7) International Air	6 years; 28 U.S.C. 2415 ...	6 years; 28 U.S.C. 2415 ...	2 years; 49 U.S.C. 40105.

(b) TIME LIMITS ON ACTIONS TAKEN BY THE FEDERAL GOVERNMENT AGAINST TSPs

[TSPs not specified in paragraph (a) of this section]

Mode	Freight	Refund for overpayment	Loss and damage
(1) All	6 years; 28 U.S.C. 2415 ...	6 years; 28 U.S.C. 2415 ...	6 years; 28 U.S.C. 2415.

■ 23. Amend § 102–118.470 by revising the section heading and introductory text to read as follows:

§ 102–118.470 Are there statutory time limits for a TSP on filing a claim with the GSA Transportation Audits Division?

Yes, a claim must be received by the GSA Transportation Audits Division or its designee (the agency where the claim arose) within 3 years beginning the day after the latest of the following dates (except in time of war):

* * * * *

■ 24. Revise § 102–118.490 to read as follows:

§ 102–118.490 What if my agency fails to settle a disputed claim with a TSP within 30 days?

(a) If your agency fails to settle a disputed claim with a TSP within 30 days, the TSP may appeal to GSA via TAMS—<https://tams.gsa.gov>.

(b) If the TSP disagrees with the administrative settlement by the GSA Transportation Audits Division, the TSP may appeal to the Civilian Board of Contract Appeals (CBCA) (See § 102–118.35 for a definition of Civilian Board of Contract Appeals (CBCA)).

■ 25. Amend § 102–118.500 by revising paragraph (a) to read as follows:

§ 102–118.500 How does my agency handle a voluntary refund submitted by a TSP?

(a) An agency must report all voluntary refunds to the GSA Transportation Audits Division (so that no Notice of Overcharge or financial offset occurs), unless other arrangements are made (e.g., charge card refunds, etc.). These reports must be sent via email to: audit.policy@gsa.gov.

* * * * *

§ 102–118.510 [Amended]

■ 26. Amend § 102–118.510 by:

■ a. In the section heading, remove the words “GSA Form 7931”; and

■ b. Removing the words “GSA Form 7931” and adding the words “Certificate of Settlement” in their place.

■ 27. Revise § 102–118.540 to read as follows:

§ 102–118.540 Who has the authority to audit, settle accounts, and/or start collection action for all transportation services provided for my agency?

(a) The Administrator of GSA has the authority and responsibility to conduct prepayment or postpayment audits of transportation bills, settle accounts, commence collection actions, and resolve transportation claims which cannot be resolved by the agency procuring the transportation services or the TSP presenting the bill. The number and types of bills audited shall be based

on the Administrator’s decision (31 U.S.C. 3726). With respect to a contract for transportation services awarded pursuant to the Federal Acquisition Regulation (FAR), such an appeal shall be adjudicated under the authority of this section using administrative procedures of GSA.

(b) The Administrator has delegated this responsibility to the Director of the GSA Transportation Audits Division because the Director has access to governmentwide data including TSP rates, agency paid TSP invoices, and transportation billings with the government. Your agency must correctly pay individual transportation invoices (See 31 U.S.C. 3351(4) Improper Payment definition).

■ 28. Revise § 102–118.545 to read as follows:

§ 102–118.545 What information must a TSP claim include?

All claims filed with GSA Transportation Audits Division either using TAMS (preferred) or via email (protests@gsa.gov) must include:

(a) The transportation document.

(b) An explanation for the claim.

(c) Any additional supporting documentation.

§ 102–118.550 [Amended]

■ 29. Amend § 102–118.550 by, in the section heading, removing the words

“an administrative” and adding the word “a” in its place.

§ 102–118.555 [Amended]

- 30. Amend § 102–118.555 by:
 - a. In the section heading, removing the word “administrative”; and
 - b. Removing the word “administrative”.
- 31. Revise § 102–118.560 to read as follows:

§ 102–118.560 What is the required format that a TSP must use to file a claim?

There is no required format for filing claims. TSPs should file a claim through TAMS or by sending the required information and documentation (see §§ 102–118.545 and 102–118.565) to GSA Transportation Audits Division via email to protests@gsa.gov.

§ 102–118.565 [Amended]

- 32. Amend § 102–118.565 by:
 - a. In the section heading, removing the words “an administrative” and adding the word “a” in their place; and
 - b. Removing the words “An administrative” and adding the word “A” in their place.
- 33. Revise § 102–118.600 to read as follows:

§ 102–118.600 When a TSP disagrees with a Notice of Overcharge resulting from a postpayment audit, what are the appeal procedures?

A TSP that disagrees with the Notice of Overcharge may submit a protest to

the GSA Transportation Audits Division via TAMS (<https://tams.gsa.gov>) or email to protests@gsa.gov.

- 34. Revise § 102–118.610 to read as follows:

§ 102–118.610 Is a TSP notified when GSA allows a claim?

Yes, the GSA Transportation Audits Division will acknowledge each payable claim using a Certificate of Settlement.

- 35. Revise § 102–118.615 to read as follows:

§ 102–118.615 Will GSA notify a TSP if they internally offset a payment?

Yes, the GSA Transportation Audits Division will notify the TSP via TAMS or email if GSA offsets a payment.

- 36. Amend § 102–118.630 by:
 - a. Revising paragraphs (a) and (b); and
 - b. Removing Note 1.

The revisions read as follows:

§ 102–118.630 How must a TSP refund amounts due to GSA?

(a) TSPs must promptly refund amounts due to GSA, preferably via TAMS or by ACH. If an ACH is not used, checks must be made payable to “General Services Administration”, including the document reference number, TSP name, bill number(s), taxpayer identification number and standard carrier alpha code, then mailed to the appropriate address listed on the Accounts and Collections web page at <https://www.gsa.gov/transaudits>.

(b) If an ACH address is needed, visit <https://www.gsa.gov/transaudits> (Accounts and Collections web page) or contact the GSA Transportation Audits Division via email at: audits.collections@gsa.gov.

- 37. Revise § 102–118.645 to read as follows:

§ 102–118.645 Can a TSP file a claim on collection actions?

Yes, a TSP may file a claim involving collection actions resulting from the transportation audit performed by the GSA directly with the GSA Transportation Audits Division. Any claims submitted to GSA will be subject to the Prompt Payment Act (31 U.S.C. 3901, *et seq.*). The TSP must file all other transportation claims with the agency out of whose activities they arose. If this is not feasible (*e.g.*, where the responsible agency cannot be determined or is no longer in existence) claims may be sent to the GSA Transportation Audits Division for forwarding to the responsible agency or for direct settlement by the GSA Transportation Audits Division. Submit claims using Transportation Audits Management System (TAMS) at <https://tams.gsa.gov> or via email to protests@gsa.gov.

[FR Doc. 2024–02791 Filed 2–15–24; 8:45 am]

BILLING CODE 6820–14–P

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

Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) 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) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by March 18, 2024. Written comments and recommendations for the proposed information collection should be submitted, identified by docket number 0535–0264, within 30 days of the publication of this notice by any of the following methods:

- *Email:* ombofficer@nass.usda.gov. Include docket number above in the subject line of the message.

- *E-fax:* 855–838–6382.

- *Mail:* Mail any paper, disk, or CD-ROM submissions to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

- *Hand Delivery/Courier:* Hand deliver to: Richard Hopper, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service (NASS)

Title: Agricultural Surveys Program.

OMB Control Number: 0535–0213.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code title 7, section 2204 which specifies that “The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .”. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

The National Agricultural Statistics Service (NASS) is requesting a substantive change to the Agricultural Surveys Program information collection request (OMB No. 0535–0213) for program changes. Every five years NASS conducts a program review following the completion of the Census of Agriculture. The program changes balance resources across all of the programs included in the annual estimating program, which represents over 400 individual reports across multiple Information Collection Requests (ICRs). This substantive change is to accommodate the field crop program changes that affect this ICR. The methodology, publication dates, burden and data collection plan do not change as result of these program changes. The changes to these surveys will not affect burden hours.

Need and Use of the Information: The surveys provide the basis for estimates of the current season's crop and livestock production and supplies of grain in storage. Crop and livestock statistics help develop a stable economic atmosphere and reduce risk for production, marketing, and distribution operations. These commodities affect the well being of the nation's farmers, commodities markets, and national and global agricultural policy. Users of agricultural statistics are farm organizations, agribusiness, state and national farm policy makers, and foreign buyers of agricultural products but the primary user of the statistical information is the producer. Agricultural statistics are also used to plan and administer other related federal and state programs in such areas as school lunch program, conservation, foreign trade, education, and recreation. Collecting the information less frequent would eliminate needed data to keep the government and agricultural industry abreast of changes at the state and national levels.

Description of Respondents: Farms and Ranches.

Number of Respondents: 491,600.

Frequency of Responses: Reporting: Quarterly; Semi-annually; Monthly; Annually.

Total Burden Hours: 184,481.

National Agricultural Statistics Service (NASS)

Title: Agricultural Resource Management Phases 1 & 2 and Chemical Use Surveys.

OMB Control Number: 0535–0218.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code title 7, section 2204 which specifies that “The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .”. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

The National Agricultural Statistics Service (NASS) is requesting a

substantive change to the Agricultural Resource Management Phases 1 & 2 and Chemical Use Surveys information collection request (OMB No. 0535–0218) for an increase in sample size due to screening for changes resulting from the reinstatement of the Tenure, Ownership and Transition of Agricultural Land (TOTAL) for 2024. Every 10 years NASS conducts the TOTAL as a follow-on survey to the 2022 Census of Agriculture and are authorized by the Food, Conservation, and Energy Act of 2008 as amended.

The Agricultural Resource Management Survey (ARMS) Phase 3 (OMB # 0535–0275) will be suspended for a period of one year. The suspended survey will be the 2024 survey that would have been conducted in 2025. The scope of the TOTAL survey is greater than that of the ARMS 3 survey. To maintain the ARMS 3 data series, data will be gleaned from the TOTAL surveys to replace the 2024 ARMS 3 data collection.

As a result of the ARMS 3 data being gleaned from TOTAL, the 2024 Integrated Screening Survey (ISS) will include the screening for the TOTAL. Current screening sample size approved for this ICR is 100,000. This substantive change documents the need for the sample size to be increased.

Need and Use of the Information: ARMS is the only annual source of whole farm information available for objective evaluation of many critical issues related to agriculture and the rural economy. This issues that will be addressed in this request are: input usage, production practices, and chemical use. Without these data, decision makers cannot analyze and report on critical issues that affect farms and farm households when pesticide regulatory actions are being considered.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 416,150.

Frequency of Responses: Reporting: Quarterly; Semi-annually; Monthly; Annually.

Total Burden Hours: 52,147.

National Agricultural Statistics Service (NASS)

Title: Water Use Survey.

OMB Control Number: 0535–0262.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code title 7, section 2204 which specifies that “The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .”. The primary objective of the National Agricultural Statistics Service

(NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

The Water Use survey program will collect information on water usage for North Carolina agricultural operations that likely use between 10,000 and 1,000,000 gallons per day. Agricultural operations who use over 1,000,000 gallons in any one day are required to report their water usage directly to North Carolina Department of Environmental Quality (NCDEQ) and are not included in this survey. All questionnaires included in this information collection will be voluntary. This project is conducted as a cooperative effort with the North Carolina Department of Agriculture and Consumer Services. Funding for this survey is being provided by NCDACS.

Need and Use of the Information: The program will help the North Carolina Department of Agriculture and Consumer Services (NCDACS) and NCDEQ fulfill the requirements of North Carolina state legislation enacted in 2008 (SL2008–0143).

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 4,000.

Frequency of Responses: Once for the even numbered years. Data are collected on the odd number years.

Total Burden Hours: 1,918.

National Agricultural Statistics Service

Title: Oregon and Washington Christmas Tree Survey—Production Year 2023.

OMB Control Number: 0535–0264.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue official State and national estimates of crop and livestock production, disposition and prices, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture and its follow-on surveys. NASS will conduct a survey of agricultural operations with Christmas Tree acreage in Oregon and Washington. Selected farmers will be asked to provide data on (1) Number of trees sold and gross sales both by species and county, (2) Number of new seedlings by species, and (3) Percentage of mortality.

General authority for these data collection activities is granted under U.S.C. Title 7, Section 2204. This survey will be conducted on a full cost

recovery basis with the Oregon Department of Agriculture and the Washington State Department of Agriculture.

Need and Use of the Information: Oregon leads the nation in Cut Christmas Tree production, with Washington also a major producer. NASS estimates have brought stability into this important Pacific Northwest industry. No other data source is available to enable growers to make decisions about production. This project involves sending a survey questionnaire to growers, following up on non-response with telephone calls, editing, analyzing, and summarizing the data. Estimates are generated, including adjustment for non-response for number of trees and value, by variety, seedlings planted by variety, geographic area, and other selected characteristics of Christmas Trees in the states of Oregon and Washington.

Description of Respondents: A sample of all active agricultural operations with Christmas Trees in Oregon and Washington. Sampling will include strata based on acreage.

Number of Respondents: 600.

Frequency of Responses: Reporting: Once a year.

Total Burden Hours: 147.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–03281 Filed 2–15–24; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meetings

AGENCY: Commission on the Social Status of Black Men and Boys (CSSBMB), U.S. Commission on Civil Rights.

ACTION: Notice of CSSBMB public business meeting.

DATES: Thursday, February 22 11:00 a.m.–12:00 p.m. EDT.

ADDRESSES: The briefing will take place virtually via YouTube.

FOR FURTHER INFORMATION CONTACT: Diamond Newman, 202–339–2371, dnewman@usccr.gov.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 116–156, 1134 Stat. 700 (2020), the Commission on the Social Status of Black Men and Boys (CSSBMB) will hold its Second Quarter Business Meeting exploring CSSBMB business items, operations, and next steps.

This business meeting is open to the public via livestream on the

Commission on Civil Rights' YouTube Page at <https://www.youtube.com/user/USCCR/videos>. (Streaming information subject to change.) Public participation is available for the event with view access, along with an audio option for listening. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on February 22 is <https://www.streamtext.net/player?event=USCCR>. Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

* Date and meeting details are subject to change. For more information on the CSSBMB or the upcoming public briefing, please visit www.usccr.gov/CSSBMB and CSSBMB's Instagram, Facebook, and X.

Briefing Agenda *

- (1) Welcome and Call to Order (11:00 a.m.–11:03 a.m.)
- (2) Business Meeting (order of business) (11:03 a.m.–11:06 a.m.)
 - (a) Quorum: (11:06 a.m.–11:09 a.m.)
 - (b) Adoption of Agenda (11:09 a.m.–11:12 a.m.)
 - (c) New Order of Business (11:12 a.m.–11:50 a.m.)
- (3) Approval of Minutes
 - (i) ii. Chair's Report
 - a. Vision and goals
 - b. State of the Commission
 - c. Introduction of New Commissioners
 - (ii) Joseph Palm of HHS
 - (iii) Commission rules
 - (iv) Upcoming highlighted events
 - (v) White House Visit (February)
 - (vi) Ribbon Cutting (May)
 - (vii) Crime Prevention (April)
 - (viii) In-Person Business Mtg (May)
 - (ix) Caucus on the Commission—Upcoming Events
 - (x) Second Annual Act Now Summit (July)
 - (xi) Fatherhood and Father's Day (June)
 - (xii) Tentative FY Business meeting proposed dates
 - (xiii) May 21, 2024
 - (xiv) ii. August 20, 2024
 - (a) iii. Director's Report
 - a. Update Profile Information
 - b. Proposed/Current Initiatives
 - i. Finalizing Annual Report
 - ii. Social Media Campaign—Black History Month
 - iii. New Commissioner Press Release
 - iv. Website Creation
 - v. 2024 Planning
 - vi. Education White Paper
 - vii. Summit and Briefing
 - (xv) iv. Open Discussion
- (4) Chair Comments/Adjourn Meeting (11:50 a.m.–12:00 p.m.)

Dated: February 14, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit, United States Commission on Civil Rights (USCCR).

[FR Doc. 2024–03394 Filed 2–14–24; 4:15 pm]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Indiana Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Indiana Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a series of public meetings via Zoom. The purpose of these meetings is to discuss, revise, and vote, as needed, on matters related to the Committee's project.

DATES:

- Monday, March 4, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, April 1, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, May 6, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, June 3, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, July 1, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, August 5, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, October 7, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, November 4, 2024, from 11 a.m.–12:30 p.m. Eastern Time
- Monday, December 2, 2024, from 11 a.m.–12:30 p.m. Eastern Time

ADDRESSES: These meetings will be held via Zoom.

Registration Link (Audio/Visual):

<https://bit.ly/3STevHy>.

Join by Phone (Audio Only): 1–833–435–1820 USA Toll Free; Webinar ID: 160 463 3231#.

FOR FURTHER INFORMATION CONTACT: Ivy Davis, Director of Eastern Regional Office and Designated Federal Officer, at ero@usccr.gov or 1–202–539–8468.

SUPPLEMENTARY INFORMATION: These Committee meetings are available to the public through the registration link above. Any interested members of the public may attend these meetings. Before adjourning each meeting, the Chair will recognize members of the

public to make brief oral statements, as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at these meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plans. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting “CC” in the meeting platform. To request additional accommodations, please email svillanueva@usccr.gov at least 10 business days prior to each meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Ivy Davis at ero@usccr.gov; please include Indiana Committee in the subject line of the transmitting email. Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–202–539–8468.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after each meeting. Records of the meetings will be available via www.facadatabase.gov under the Commission on Civil Rights, Indiana Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at svillanueva@usccr.gov.

Agenda

- I. Meeting Announcement & Roll Call
- II. Welcome
- III. Project Planning
- IV. Other Matters
- V. Public Comment
- VI. Adjourn

Dated: February 12, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–03206 Filed 2–15–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE**Census Bureau****Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Generic Clearance for Collection of State Administrative Records Data**

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed extension of the collection of state level administrative records data, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 16, 2024.

ADDRESSES: Interested persons are invited to submit written comments by email to Jenny Aramony at adrm.pra@census.gov. Please reference 'Generic Clearance for Collection of State Administrative Records Data' in the subject line of your comments. You may also submit comments, identified by Docket Number USBC-2024-0001, to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Jenny Aramony, U.S. Census Bureau, 4600

Silver Hill Road, Washington, DC 20233-8400 at (301) 763-8715.

SUPPLEMENTARY INFORMATION:**I. Abstract**

The U.S. Census Bureau plans to request clearance for acquiring State administrative records data in order to improve efficiency and accuracy in our data collections, and to improve measures of the population and economy. The Census Bureau has undertaken research projects to integrate and link Census Bureau data from current surveys and censuses with State administrative records data.

The Census Bureau uses State administrative records data linked with other survey and census records, including but not limited to, data from the Survey of Income and Program Participation (SIPP), the Current Population Survey (CPS) and the American Community Survey (ACS) to conduct research and improve operations. The Census Bureau benefits from these projects by improving data quality, and producing modelbased estimates, improved edits and allocations, and studies of program participation over time. Data providers have benefited through access to tabulated data and reports to better administer their programs.

The Census Bureau encourages the District of Columbia and all 50 states to share administrative records data generally associated with, but not limited to: nutrition and food assistance programs, including the Supplemental Nutrition Assistance Program (SNAP) and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC); and welfare programs, including child care subsidy; household self-sufficiency programs, including low income energy assistance programs and Temporary Assistance for Needy Families (TANF). Data sharing and analysis of linked files are solely for statistical purposes, not for program enforcement. All State administrative records data are and will remain confidential under title 13, United States Code, section 9, whether in their original form or when comingled or linked.

Linking records across programs, across states, or over time will be accomplished using a unique linkage identifier called a Protected Identification Key (PIK). Processing to assign a PIK to each person record involves matching based on combinations of name, address, sex, date of birth, and Social Security Number (SSN) data, as available. The person validation and PIK processing has been used by other Census Bureau

research and operations projects. Only Census Bureau staff conducting the record linkage have access to files with Personally Identifiable Information, and access to those files assigned a PIK is limited to individuals with a need to know who have met the requirements of Title 13, United States Code, and have appropriate security clearances.

The Census Bureau makes summary statistics and analyses using the State administrative records data publicly available. This information assists State Agencies in developing better measures of program participation, poverty, and inequality, and understanding the demographic characteristics of participants. The analyses help State Agencies understand variation in program participation across demographic subgroups and sub-state geographies, review enrollment rates for those eligible for assistance, analyze the effects of state programs on a variety of outcomes, and improve program administration in determining initial eligibility, establishing recertification periods, and expanding outreach in underserved populations and areas.

II. Method of Collection

The Census Bureau will contact the State Agencies to discuss uses of State administrative records data. The State Agencies will enter data sharing agreements with the Census Bureau to provide administrative records data. The State Agency will transfer State administrative records to the Census Bureau via secure File Transfer Protocol or appropriately encrypted CD-ROM or DVD-ROM.

III. Data

OMB Control Number: 0607-0995.

Form Number(s): None.

Type of Review: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection.

Affected Public: State Governments.

Estimated Number of Respondents: 51 states.

Estimated Time per Response: 75.

Estimated Total Annual Burden Hours: 3,825.

Estimated Total Annual Cost to Public: \$99,450 (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. 6.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–03207 Filed 2–15–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Offsets in Military Exports

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this

notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 16, 2024.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at mark.crace@bis.doc.gov or to PRAComments@doc.gov. Please reference OMB Control Number 0694–0084 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202–482–8093 or by email at mark.crace@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is required by the Defense Production Act (DPA). The DPA requires U.S. firms to furnish information to the Department of Commerce regarding offset agreements exceeding \$5,000,000 in value associated with sales of weapon systems or defense-related items to foreign countries or foreign firms. Offsets are industrial or commercial compensation practices required as a condition of purchase in either government-to-government or commercial sales of defense articles and/or defense services as defined by the Arms Export Control Act and the International Traffic in Arms Regulations. Such offsets are required by most major trading partners when purchasing U.S. military equipment or defense related items.

II. Method of Collection

Electronic or on paper.

III. Data

OMB Control Number: 0694–0084.

Form Number(s): 0694–0084.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 30.

Estimated Time per Response: 12 hours.

Estimated Total Annual Burden Hours: 360.

Estimated Total Annual Cost to Public: 9,000.

Respondent's Obligation: Mandatory.
Legal Authority: Defense Production Act of 1950, Section 309.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–03303 Filed 2–15–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD539]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Lutak Dock Replacement Project, Haines, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as

amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Haines Borough to incidentally harass marine mammals during construction activities associated with a Lutak Dock Replacement project in Haines, Alaska.

DATES: This authorization is effective from June 1, 2024, through May 31, 2025.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the 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 proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On July 10, 2023, NMFS received a request from Haines Borough for an IHA to take marine mammals incidental to pile driving involving impact, vibratory, and down-the-hole (DTH) drilling to replace the Lutak Dock. Following NMFS’ review of the application, Haines Borough submitted a revised version on October 11, 2023. The application was deemed adequate and complete on October 16, 2023.

Haines Borough’s request was for take of six species of marine mammals by Level B harassment and, for a subset of three of these species, Level A harassment. Neither Haines Borough nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Activity

Haines Borough will encapsulate the existing Lutak Dock structure with a new dock structure of similar design. In-water construction activities associated with the project will include impact pile driving, vibratory pile driving and removal, and DTH installation. Pile removal will consist of 24 16-inch (in) steel pipe piles (41 centimeters (cm)) that make up the 4 mooring dolphins and 1 24-in (61-cm) steel guide pile. A template frame will then be welded to 42 36-in (91-cm) temporary piles that are capable of holding 10 permanent piles in each section. The template frame will be used to position the 180 42-in (107-cm) permanent piles across the length of the dock. Up to 10 permanent piles will be set at a time, before moving the template to the next position to install the next 10 permanent piles. A permanent 55.5-in (140-cm) sheet pile wall will be installed and attached to the permanent piles to make up the new dock return walls. It is expected to take up to 234 non-consecutive days to complete the pile driving and removal activities.

A detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed IHA (88 FR 78310, November 15, 2023). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS’ proposal to issue an IHA to Haines Borough was published in the **Federal Register** on November 15, 2023 (88 FR 78310). That notice described, in detail, Haines Borough’s activity, the marine mammal

species that may be affected by the activity, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments.

During the 30-day public comment period, NMFS did not receive any public comments.

Changes From the Proposed IHA to Final IHA

In table 7 of the proposed IHA **Federal Register** notice (88 FR 78310, November 15, 2023) Level A and Level B harassment zones for impact installation of 42-in. piles were incorrect. These values have been corrected in table 6 of this notice. Take estimates and mitigation measures were considered using the correct source level and harassment zones and thus remain unchanged in this notice.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS’ Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS’ website (<https://www.fisheries.noaa.gov/find-species>).

Table 1 lists all species or stocks for which take is expected and authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS’ SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from

anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular

study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in

NMFS' Alaska SARs (Young *et al.*, 2023). All values presented in table 1 are the most recent available at the time of publication and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 1—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES ¹

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Artiodactyla—Infraorder Cetacea—Mysticeti (baleen whales)						
<i>Family Balaenopteridae</i> (rorquals):						
Humpback whale	<i>Megaptera novaeangliae</i>	Hawai'i	-,-, N	11,278 (0.56, 7,265, 2020)	127	27.09
		Mexico-North Pacific	T, D, Y	N/A (N/A, N/A, 2006)	UND	0.57
Odontoceti (toothed whales, dolphins, and porpoises)						
<i>Family Delphinidae:</i>						
Killer whale	<i>Orcinus orca</i>	Eastern North Pacific Alaska Resident.	-,-, N	1,920 (N/A, 1,920, 2019)	19	1.3
		Eastern Northern Pacific Northern Resident.	-,-, N	302 (N/A, 302, 2018)	2.2	0.2
		West Coast Transient	-,-, N	349 (N/A, 349, 2018)	3.5	0.4
<i>Family Phocoenidae (porpoises):</i>						
Harbor porpoise	<i>Phocoena phocoena</i>	Northern Southeast Alaska Inland Waters.	-,-, N	1,619 (0.26, 1,250, 2019)	13	5.6
Dall's Porpoise	<i>Phocoenoides dalli</i>	Alaska	-,-, N	UND (UND, UND, 2015)	UND	37
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions):</i>						
Steller sea lion	<i>Eumetopias jubatus</i>	Eastern DPS ⁵	-,-, N	43,201 (N/A, 43,201, 2017) ...	2,592	112
		Western DPS	E, D, Y	52,932 (N/A, 52,932, 2019) ...	318	254
<i>Family Phocidae (earless seals):</i>						
Harbor Seal	<i>Phoca vitulina</i>	Lynn Canal/Stephens Passage.	-,-, N	13,388 (N/A, 11,867, 2016) ...	214	50

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://www.marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>; Committee on Taxonomy (2022)).

² ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports/>. CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

⁵ Distinct Population Segment (DPS).

A detailed description of the species likely to be affected by the Lutak Dock Replacement project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (88 FR 78310, November 15, 2023); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (<https://www.fisheries.noaa.gov/find-species>) for

generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine

mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower

bound was deemed to be biologically implausible and the lower bound from

Southall *et al.* (2007) retained. Marine mammal hearing groups and their

associated hearing ranges are provided in table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	275 Hz to 160 kHz
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.*, 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from Haines Borough's construction activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the project area. The notice of proposed IHA (88 FR 78310, November 15, 2023) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from Haines Borough's construction activities on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (88 FR 78310, November 15, 2023).

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes authorized through the final IHA, which will inform both NMFS' consideration of "small numbers," and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of 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).

Authorized takes would primarily be by Level B harassment, as use of the construction equipment (*i.e.*, pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency cetaceans and phocids, because predicted auditory injury zones are larger and beyond Haines Borough's capability to reasonably monitor. Auditory injury is unlikely to occur for other species groups, based on the combination of expected occurrence and monitoring capabilities relative to estimated Level A harassment zone sizes. The mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential

takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed by varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, Southall *et al.*, 2021, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1

micropascal (re 1 μ Pa) for continuous (e.g., vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (e.g., seismic airguns) or intermittent (e.g., scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by temporary threshold shift (TTS) as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

Haines Borough's activity includes the use of continuous (vibratory pile

driving) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120- and 160-dB re 1 μ Pa are applicable. DTH systems have both continuous and intermittent (impulsive) components as discussed in the proposed IHA **Federal Register** notice (88 FR 78310, November 15, 2023) in the Description of Sound Sources section. When evaluating Level B harassment, NMFS recommends treating DTH as a continuous source and applying the RMS SPL thresholds of 120-dB re 1 μ Pa.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0 of Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different

types of sources (impulsive or non-impulsive). The Haines Borough's construction includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources. As described above, DTH includes both impulsive and non-impulsive characteristics. When evaluating Level A harassment, NMFS recommends treating DTH as an impulsive source.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance>.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_E,LF,24h$: 183 dB	Cell 2: $L_E,LF,24h$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_E,MF,24h$: 185 dB	Cell 4: $L_E,MF,24h$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_E,HF,24h$: 155 dB	Cell 6: $L_E,HF,24h$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_E,PW,24h$: 185 dB	Cell 8: $L_E,PW,24h$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_E,OW,24h$: 203 dB	Cell 10: $L_E,OW,24h$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the project. Marine mammals are expected to be affected via sound generated by the primary components of the project (i.e., impact pile driving, vibratory pile driving and removal, DTH). The maximum (underwater) area ensonified above the thresholds for behavioral harassment referenced above is 20.86 kilometers² (12.96 miles²), and will consist of the entire area of Lutak Inlet (see Figure 20 in the Haines Borough's

application). Additionally, vessel traffic and other commercial and industrial activities in the project area may contribute to elevated background noise levels which may mask sounds produced by the project.

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B \times \log_{10} (R_1/R_2)$$

Where:

TL = transmission loss in dB

B = transmission loss coefficient

R_1 = the distance of the modeled SPL from

the driven pile, and
 R_2 = the distance from the driven pile of the initial measurement

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB reduction in sound level for each doubling of distance from the source ($20 \times \log[\text{range}]$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting

in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 \times \log[\text{range}]$). A practical spreading value of 15 is often used under conditions, such as the project site, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that will lie between spherical and cylindrical spreading loss conditions. Practical spreading loss is assumed here.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical

environment in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, the applicant and NMFS used acoustic monitoring data from other locations to develop proxy source levels for the various pile types, sizes and methods. The project includes vibratory, impact, and DTH pile installation of steel pipe and sheet piles and vibratory removal of steel pipe piles. Source levels for impact installation of 36-in steel piles are used as a proxy for 42-in

steel piles, as 36-in source levels are higher than those available for 42-in piles. Using these higher values is the more conservative approach for mitigation measures and take estimate calculations. NMFS consulted multiple sources to determine valid proxy source levels for the impact installation of sheet piles, as indicated in table 4. This is the best available data for sheet pile source levels and is based on 24-in sheet piles used for a project in California. Source levels for each pile size and driving method are presented in table 4.

TABLE 4—PROXY SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile size	Method	Proxy source level			Literature source
		dB RMS re $1\mu\text{Pa}$	dB SEL * re $1\mu\text{Pa}^2\text{sec}$	dB peak re $1\mu\text{Pa}$	
16-in	Vibratory	161	N/A	N/A	Navy 2015.
24-in	Vibratory	161	N/A	N/A	Navy 2015.
36-in	Vibratory	166	N/A	N/A	Navy 2015.
42-in	Vibratory	170	N/A	N/A	Illingworth and Rodkin, 2019.
55.5-in sheet pile	Vibratory	162	N/A	N/A	Molnar <i>et al.</i> 2020.
36-in	Impact	192	184	211	Navy 2015.
42-in	Impact	192	184	211	Navy 2015.
55.5-in sheet pile	Impact	190	180	205	Caltrans 2015.
42-in	DTH	174	164	194	NMFS 2022.

* Sound exposure level (SEL)

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions

included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as impact or vibratory pile

driving and removal and DTH, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it will be expected to incur PTS. Inputs used in the optional User Spreadsheet tool (table 5), and the resulting estimated isopleths and the calculated Level B harassment isopleth (table 6), are reported below. For source levels of each pile please refer to table 4.

TABLE 5—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS

Pile size and installation method	Spreadsheet tab used	Weighting factor adjustment (kHz)	Number of strikes per pile	Number of piles per day	Activity duration (minutes)
16-in vibratory removal	A.1 Vibratory pile driving	2.5	N/A	4	45
24-in vibratory removal	A.1 Vibratory pile driving	2.5	N/A	1	45
36-in vibratory installation (temporary)	A.1 Vibratory pile driving	2.5	N/A	4	15
36-in vibratory removal (temporary)	A.1 Vibratory pile driving	2.5	N/A	4	15
42-in vibratory installation	A.1 Vibratory pile driving	2.5	N/A	4	45
55-in sheet pile vibratory installation	A.1 Vibratory pile driving	2.5	N/A	6	30
36-in impact installation (temporary)	E.1 Impact pile driving	2	900	4	N/A
42-in impact installation	E.1 Impact pile driving	2	1,500	4	N/A
55-in sheet pile impact installation	E.1 Impact pile driving	2	900	6	N/A
42-in DTH installation	E.2 DTH systems	2	324,000	2	N/A

TABLE 6—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Phocids	Otariids	
16-in vibratory removal	14.2	1.3	21.8	8.6	0.6	5,412

TABLE 6—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS—Continued

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Phocids	Otariids	
24-in vibratory removal	5.6	0.5	8.3	3.4	0.2	
36-in vibratory installation (temporary)	14.7	1.3	21.8	8.9	0.6	11,659
36-in vibratory removal (temporary)	14.7	1.3	21.8	8.9	0.6	
42-in vibratory installation *	56.6	5.0	83.6	34.4	2.4	21,544
55-in sheet pile vibratory installation	16.6	1.5	24.5	10.1	0.7	6,310
36-in impact installation (temporary)	2,734.9	97.3	3,257.7	1,463.6	106.6	1,359
42-in impact installation	3,844.5	136.7	4,579.4	2,057.4	149.8	1,359
55-in sheet pile impact installation	1,939.4	69.0	2,310.1	1,037.9	75.6	1,000
42-in DTH installation	4,046.9	143.9	4,820.5	2,165.7	157.7	39,811

* Harassment zones updated from the proposed IHA.

Marine Mammal Occurrence

In this section NMFS provides information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

When available, peer-reviewed scientific publications were used to estimate marine mammal abundance in the project area. Data from monitoring reports from previous projects in Lutak and Skagway were used. However, scientific surveys and resulting data, such as population estimates, densities, and other quantitative information, are lacking for some marine mammal populations and most areas of southeast Alaska, including Lutak Inlet. Therefore, Haines Borough additionally gathered qualitative information from discussions with knowledgeable local people in the Haines area. Assumptions regarding the size of expected groups of different species, and the frequency of occurrence of those groups, were provided by Haines Borough on the basis of the aforementioned information. NMFS has reviewed the available information and concurs that these choices are reasonable.

Here we describe how the information provided is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized. Since reliable densities are not available, the take numbers are based on the assumed maximum number of animals in a group at a given time and the occurrence of those groups per day multiplied by the duration of each activity. Tables for each species are presented to show the calculation of take during the project. The take calculation for this project is:

Incidental take estimate = number of individuals in a group × groups per day × days of pile-related activity

Humpback Whale

Humpback whale presence in Lutak is irregular year-round. From mid-May

through September whales are assumed to occur in groups of two and from October to April in groups of one. It is expected that in early summer (mid-May through July) one group every 2 days may occur and at all other times of the year one group every 10 days will occur in the project area (Solstice AK, 2023; Happywhale, 2023). Therefore, using the equation given above, the total number of Level B harassment takes for humpback whales will be 26. Given that 2 percent of the humpback whales in southeast Alaska are expected to be members of the Mexico stock (Wade *et al.*, 2016), 1 take is assumed to be from the Mexico stock and 25 takes from the Hawaii stock.

The largest Level A harassment zone for humpback whales extends 4,050-m from the noise source (table 6). All construction work will be shut down prior to a humpback whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the infrequent occurrence of humpback whales in the project area and shutdown requirements, no take by Level A harassment is anticipated or authorized for humpback whales.

Killer Whale

Killer whales occur in the Lutak Inlet year round with higher occurrences in the spring. Group sizes of 15 animals are expected with 1 group every 20 days from mid-March through May and 1 group every 30 days for the remainder of the year (Hart Crowser, Inc. and KPFF Consulting Engineers 2016). There are three stocks of killer whales that may be present in the project area, with the following proportions of overall killer whale occurrence expected: Alaska Residents, 75 percent; West Coast Transients, 13 percent; and Northern Residents, 12 percent (section 6 of the IHA application). The applicant estimated these occurrence proportions by determining the total number of animals in all three stocks and dividing

that number by the number of animals in a given stock. Therefore, with 130 expected total takes by Level B harassment, 103 takes are expected to be from the Alaska Resident stock, 19 takes are expected from the West Coast Transient stock, and 16 takes are expected from the Northern Resident stock.

The largest Level A harassment zone for killer whales extends 150-m from the noise source (table 6). Killer whales are generally conspicuous and protected species observers (PSOs) are expected to detect killer whales and implement a shutdown before the animals enter the Level A harassment zone. Therefore, takes by Level A harassment are not anticipated or authorized.

Harbor Porpoise

Harbor porpoise are present year round in the Lynn Canal and are expected to be present in groups of two every 30 days at the project site. Haines Borough requested a total of 29 takes of harbor porpoise for the duration of the project. Of the 29 takes it is expected that 13 of those takes could be by Level A harassment, over 153 days of impact installation of 36-in, 42-in, and 55-in sheet piles and DTH activities. For construction activities that are of short duration and the take estimate was below the expected group size, the expected group size (*e.g.*, two animals) was used as a proxy for take calculations for those activities. The remaining 16 takes are expected to be by Level B harassment.

Harbor porpoises are known to be an inconspicuous species and are challenging for PSOs to sight, making any approach to a specific area potentially difficult to detect. The largest Level A harassment zone results from impact driving of 42-in piles, and extends 4,820.5-m from the source for high frequency cetaceans (table 6). The IHA requires a distance of 200-m as a shutdown zone, given the difficulty of observing harbor porpoise at greater

distances (see Mitigation section). Therefore, some take by Level A harassment is expected.

Dall's Porpoise

Groups of 4 Dall's porpoise are expected to occur once every 30 days during the project (Dahlheim *et al.*, 2009), resulting in an estimate of 31 takes by Level B harassment. Although no Dall's porpoise were observed during recent monitoring of other projects in the area, tour boat operators occasionally observe Dall's porpoise in Taiya Inlet (SolsticeAK, 2023). Therefore, the applicant has requested authorization of take as described above. NMFS concurs with this request and authorizes the take.

The largest Level A harassment zone for Dall's porpoise extends 4,820.5-m from the source during DTH installation of 42-in piles (table 6). Although Haines Borough will implement a significantly smaller shutdown zone (*i.e.*, 200-m), given the low likelihood of occurrence of Dall's porpoises in the area take by Level A harassment is not anticipated and is not authorized.

Steller Sea Lion

Steller sea lions are frequently observed in the project area. Group sizes vary during seasonal fish runs in the area. Groups of 40 animals per day are expected from mid-March through May when animals frequent the project site, including the Taiya point haulout. At other times of the year groups of two animals per day are expected in the project area.

During the impact installation of 36-in and 42-in piles and the DTH installation of 42-in piles, groups of 2

sea lions per day are expected to occur within the respective Level A harassment zones over 146 days associated with these activities. On this basis, NMFS authorizes 292 takes of Steller sea lions by Level A harassment. Given that 1.4 percent of Steller sea lions are members of the ESA listed western DPS in the project area, 4 of the 292 takes by Level A harassment will likely be western DPS individuals. The largest Level A harassment zone for Steller sea lions is 150-m (table 6) but it may be difficult for PSOs to view Steller sea lions at the outer edges of the zone and therefore some take by Level A harassment is expected.

Larger harassment zones associated with Level B harassment will encompass the Taiya point haulout. It is expected that groups of 40 Steller sea lions per day over 75 days of vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-in piles which will equate to 3,000 takes by Level B harassment. At other times of the year when the Taiya point haulout is not used, group size will be two sea lions per day. During this period the applicant will complete work over 151 days for vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-in piles which will equate to 302 takes by Level B harassment.

Harbor Seal

Harbor seals are common in the project area year round. The applicant and NMFS expect groups of 100 animals from March through May when animals are more frequent feeding at the mouth of the Chilkoot River. At other times of

the year, groups of five animals are expected in the project area (SolsticeAK 2023).

During impact installation of 36-in, 42-in, and 55-in sheet piles and DTH installation of 42-in piles it is expected that one group of five harbor seals every 10 days will occur. Over 153 days of activity, 79 total takes by Level A harassment may occur. For construction activities that are of short duration and the take estimate was below the expected group size, the expected group size (*e.g.*, five animals) was used as a proxy for take calculations for those activities. The largest Level A harassment zone results from impact driving of 42-in piles extends 2,057 m from the source for phocids (table 6). The IHA requires a 200-m shutdown zone, given the difficulty of observing harbor seals at greater distances (see Mitigation section). Therefore, take by Level A harassment is expected.

Similar to Steller sea lions the larger Level B harassment zones will encompass the mouth of the Chilkoot River where larger aggregations of harbor seals are known to occur. It is expected that groups of harbor seals of 100 every 10 days over 75 days of vibratory installation of all pile types, impact installation of all pile types, and DTH installation of 42-in piles, which will equate to 750 takes by Level B harassment. During other times of the year the applicant expects groups of five animals every 10 days over a 151 day period for vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-in piles. This will result in 827 takes by Level B harassment.

TABLE 7—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance ^a	Level A	Level B	Total take	Take as a percentage
Humpback Whale	Mexico	Unknown	0	1	1	N/A
	Hawaii	11,278	0	25	25	0.2
Killer Whale	Alaska Resident	1,920	0	103	103	5.4
	West Coast Transients	349	0	19	19	5.4
	Eastern North Pacific Northern Residents.	302	0	16	16	5.3
Harbor Porpoise	Northern Southeast Alaska	1,619	13	16	29	1.8
Dall's Porpoise	Alaska	UKN	0	31	31	N/A
Steller sea lion	Western DPS	52,932	4	33	37	<0.1
	Eastern DPS	43,201	288	2,319	2,607	6.0
Harbor Seal	Lynn Canal/Stephens Passage.	13,388	79	827	906	6.8

^a Stock or DPS size is best estimate of population size (Nbest) according to NMFS 2022 Final Stock Assessment Reports.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of

taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds,

and areas of similar significance. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological)

of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if

implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The following measures will apply to Haines Borough's mitigation requirements:

Implementation of Shutdown Zones—For all pile driving/removal activities, Haines Borough will implement shutdowns within designated zones. The purpose of a shutdown zone is generally to define an area within which shutdown of activity will occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Implementation of shutdowns will be used to avoid or minimize incidental Level A harassment takes from vibratory, impact, and DTH pile removal and installation (table 8).

For all pile driving/removal activities, a minimum 10-m shutdown zone must be established. NMFS has recommended shutdown zones of 200-m for high-frequency cetaceans and phocids, despite significantly larger estimated Level A harassment zones, in order to prescribe implementation of a zone that may be reasonably observed under typical conditions for these cryptic species. It is reasonable to expect that these species will be difficult to detect from distances further than 200-m by PSOs (table 8). All other shutdown zones for pile driving and removal activities are based on the Level A harassment zones and therefore vary by pile size and marine mammal hearing group (table 6). The placement of PSOs during all pile driving activities (described in detail in the Monitoring and Reporting section) will ensure the full extent of shutdown zones are visible to PSOs.

TABLE 8—SHUTDOWN ZONES DURING PILE INSTALLATION AND REMOVAL

Activity	Pile size	Minutes or strikes per pile	Piles per day	Shutdown zones (m)				
				LF cetaceans	MF cetaceans	HF cetaceans	Phocids	Otariids
Vibratory Removal	16-in	45 min	4	15	10	30	10	10
	24-in	45 min	1	10				
Vibratory Installation	36-in (temporary)	15 min	4	15	10	30	10	10
	36-in (temporary)	15 min	4	15	10	30	10	10
	42-in	45 min	4	60	10	85	35	10
	55-in sheet pile	30 min	6	20	10	25	10	10
Impact Installation	36-in (temporary)	900 strikes	4	2,735	110	200	200	110
	42-in	1,500 strikes	4	3,845	150			150
	55-in sheet pile	900 strikes	6	1,940	70			80
DTH drilling	42-in	300 min/324,000 strikes	2	4,050	145			160

Establishment of Monitoring Zones—Haines Borough has identified monitoring zones correlated with the larger of the Level B harassment or Level A harassment zones. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. In some cases the calculated monitoring zones are smaller than the Level A shutdown zones as presented in table 8. This is due to the project area being bounded by land to 7,000-m on the western most shore of the inlet and 5,820-m on the eastern shore. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential cessation of activity should the animal enter the shutdown zone. PSOs will monitor the entire visible area to maintain the best sense of where animals are moving relative to the zone boundaries defined

in tables 8 and 9. Placement of PSOs on the shorelines around Lutak Inlet allow PSOs to observe marine mammals within and near the inlet. The applicant may also voluntarily place a PSO on a skiff in Taiya Inlet if safe conditions allow for such activity.

TABLE 9—MARINE MAMMAL MONITORING ZONE

Activity	Monitoring zone (m)
Vibratory removal of 16-in and 24-in piles	5,425
Vibratory installation and removal of 36-in temporary piles	7,000
Vibratory installation of 42-in piles	7,000
Vibratory installation of 55-in sheet piles	6,310
Impact installation of 36-in temporary piles	*1,360

TABLE 9—MARINE MAMMAL MONITORING ZONE—Continued

Activity	Monitoring zone (m)
Impact installation of 42-in piles	*1,360
Impact installation of 55-in sheet piles	1,000
DTH installation of 42-in piles	7,000

*Where Level A shutdown zones are larger than the Level B harassment zones.

Soft Start—The use of soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors will be required to provide an initial set of strikes from the hammer at reduced energy, with each strike followed by a 30-second

waiting period. This procedure will be conducted a total of three times before impact pile driving begins. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30-minutes or longer. Soft start is not required during vibratory pile driving and removal activities.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal of 30-minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30-minutes. The shutdown zone will be considered cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15-minutes. If the monitoring zone has been observed for 30-minutes and marine mammals are not present within the zone, soft-start procedures can commence and work can continue even if visibility becomes impaired within the monitoring zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, activities may begin. No work may begin unless the entire shutdown zone is visible to the PSOs. If work ceases for more than 30-minutes, the pre-activity monitoring of both the monitoring zone and shutdown zone will commence.

Based on our evaluation of the applicant's measures, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the

most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (e.g., source characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

Monitoring shall be conducted by NMFS-approved observers in accordance with the monitoring plan (appendix C of the IHA application) and section 5 of the IHA. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. Observer training must be provided prior to project start, and shall include instruction on species identification (sufficient to distinguish the species in the project area), description and categorization of observed behaviors and interpretation of behaviors that may be construed as being reactions to the specified activity, proper completion of data forms, and other basic components of biological monitoring, including tracking of observed animals or groups of animals such that repeat sound

exposures may be attributed to individuals (to the extent possible).

Monitoring will be conducted 30-minutes before, during, and 30-minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30-minutes.

A minimum of one PSO will be on duty during all barge movements and other in-water construction activities and a minimum of three PSOs during all pile driving activities. Locations from which PSOs will be able to monitor for marine mammals are readily available from publicly accessible shore side areas at the project site, Lutak Road at a beach across from Takshanuk Mountain trail, and along the shoreline just south of Tanani Point along Lutak Road. PSOs will monitor for marine mammals entering the harassment zones.

PSOs will scan the waters using binoculars and will use a handheld range-finder device to verify the distance to each sighting from the project site. All PSOs will be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator via a radio. Haines Borough will adhere to the following observer qualifications:

(i) PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;

(ii) One PSO will be designated as the lead PSO or monitoring coordinator and that observer must have prior experience working as an observer;

(iii) Other observers may substitute education (degree in biological science or related field) or training for experience; and

(iv) Haines Borough must submit observer Curriculum Vitae for approval by NMFS.

Additional recommended observer qualifications include:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

A draft marine mammal monitoring report will be submitted to NMFS within 90 days after the completion of pile driving and removal activities. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.*, impact driving) and for each pile or total number of strikes for each pile (impact driving);
- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; time of sighting; identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of

the group if there is a mix of species; distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); estimated number of animals (min/max/best estimate); estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); animal's closest point of approach and estimated time spent within the harassment zone; and description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

- Number of marine mammals detected within the harassment zones, by species; and
- Detailed information about any implementation of any mitigation triggered (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, Haines Borough will immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report will include the following information:

- Description of the incident;
- Environmental conditions (*e.g.*, Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities will not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Haines Borough to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Haines Borough

will not be able to resume their activities until notified by NMFS.

In the event that Haines Borough discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.*, in less than a moderate state of decomposition as described in the next paragraph), Haines Borough will immediately report the incident to the Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report will include the same information identified in the paragraph above. Activities will be able to continue while NMFS reviews the circumstances of the incident. NMFS will work with Haines Borough to determine whether modifications in the activities are appropriate.

In the event that Haines Borough discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Haines Borough will report the incident to the Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. Haines Borough will provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact 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 (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as

effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (e.g., as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in table 7, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving and removal activities associated with the project as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from pile driving and removal. Potential takes could occur if individuals of these species are present in zones ensonified above the thresholds for Level A or Level B harassment identified above when these activities are underway.

Take by Level A and Level B harassment will be due to potential behavioral disturbance, TTS, and PTS. No serious injury or mortality is anticipated or authorized given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. Take by Level A harassment is only anticipated for harbor porpoise, Steller sea lions, and harbor seal. Take by Level A harassment of the ESA-listed western DPS of Steller sea lions is expected to be a very small portion of the overall DPS (<0.1 percent). Impacts to affected individuals of the western DPS are not expected to result in population-level impacts. The potential for harassment is minimized through the construction method (i.e., use of direct pull removal or vibratory methods to the extent practical) and the implementation of the

planned mitigation measures (see Mitigation section).

In addition to the expected effects resulting from Level B harassment, we anticipate that harbor porpoises, Steller sea lions, and harbor seals may sustain some limited Level A harassment in the form of auditory injury. However, animals in these locations that experience PTS will likely only receive slight PTS, i.e., minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by pile driving, i.e., the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal will lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. As described above, we expect that marine mammals will be likely to move away from a sound source that represents an aversive stimulus, especially at levels that will be expected to result in PTS, given sufficient notice through use of soft start.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities will not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish or invertebrates to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities, the relatively small area of the habitat that may be affected, and the availability of nearby habitat of similar or higher value, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. The haulout location at Taiya Point will be affected by the project for foraging Steller sea lions and occasionally harbor seals. Currently, the Taiya Point haulout location is not known to be a pupping location for Steller sea lions or harbor seals but are important areas throughout the year. Steller sea lions and to a lesser extent harbor seals at this haulout will likely result in repeated exposure of the same animals. Repeated exposures of individuals to this pile driving activity could cause Level A and Level B harassment but are unlikely to considerably disrupt foraging behavior or result in significant decrease in fitness, reproduction, or survival for the affected individuals.

In summary and as described above, the following factors support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
 - Any Level A harassment exposures (i.e., to harbor seals, harbor porpoise, and Steller sea lions, only) are anticipated to result in slight PTS (i.e., of a few decibels), within the lower frequencies associated with pile driving;
 - The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that will not result in fitness impacts to individuals;
 - The ensonified areas from the project are very small relative to the overall habitat ranges of all species and stocks;
 - The lack of anticipated significant or long-term negative effects to marine mammal habitat or any other areas of known biological importance; with the exception of the haulout location at Taiya Point; and
 - The mitigation measures are expected to reduce the effects of the specified activity to the level of least practicable adverse impact.
- Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 7 demonstrates the number of animals that could be exposed to the received noise levels that could cause harassment for the work in Lutak Inlet. Our analysis shows that less than 6.8 percent of each affected stock could be taken by harassment. The numbers of animals to be taken for these stocks will be considered small relative to the relevant stock's abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an “unmitigable adverse impact” on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined “unmitigable adverse impact” in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

In the Haines area sea lions and harbor seals are available for subsistence harvest under the MMPA. Limited subsistence harvests of marine mammals near the community of Haines has occurred in the past, with the most recent recorded/documented harvests of marine mammals in Haines in 2012 and in nearby Klukwan in 2014. The activity will take place in Lutak Inlet, and no activities overlap with current subsistence hunting areas; therefore, there are no relevant subsistence uses of marine mammals adversely impacted by this action. The project is not likely to adversely impact the availability of any marine mammal species or stocks that are commonly used for subsistence purposes or to impact subsistence harvest of marine mammals in the region.

Based on the description of the specified activity, the measures described to minimize adverse effects

on the availability of marine mammals for subsistence purposes, and the mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from Haines Borough's activities.

Endangered Species Act

There are two marine mammal species (Mexico DPS humpback whale and western DPS Steller sea lion) that NMFS is authorizing take in the project area that are listed as threatened and endangered under the ESA. The NMFS Alaska Regional Office issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to Haines Borough under section 101(a)(5)(D) of the MMPA by the NMFS Permits and Conservation Division. The Biological Opinion concluded that the action is not likely to jeopardize the continued existence of western DPS Steller sea lions, and is not likely to destroy or adversely modify Mexico DPS humpback whale and western DPS Steller sea lion critical habitats.

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 evaluate our proposed action (*i.e.*, the issuance of an IHA) and alternatives with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 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. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to Haines Borough for the potential harassment of small numbers of six marine mammal species incidental to the Lutak Dock replacement project in Haines, AK, that includes the previously explained mitigation, monitoring and reporting requirements.

Dated: February 12, 2024.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2024–03251 Filed 2–15–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD731]

Mid-Atlantic Fishery Management Council (MAFMC) and New England Fishery Management Council (NEFMC); Joint Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The MAFMC and NEFMC will jointly hold a public meeting (webinar) of the Spiny Dogfish and Monkfish Advisory Panels to review potential sturgeon bycatch reduction measures. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Tuesday, March 5, 2024, from 1 p.m. to 5 p.m.

ADDRESSES: Webinar connection information will be posted to the MAFMC's website calendar prior to the meeting at www.mafmc.org.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; www.mafmc.org.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Councils' Monkfish and Spiny Dogfish Advisory Panels will meet jointly to discuss: The range of sturgeon bycatch reduction alternatives; the draft impact analyses for the alternatives; recommendations for the Councils and their Spiny Dogfish and Monkfish Committees; and other business, as necessary.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 13, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-03306 Filed 2-15-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD730]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Council) and its advisory bodies will meet March 5–11, 2024 in Fresno, CA and via webinar. The Council meeting will be live streamed with the opportunity to provide public comment remotely. The following groups will meet in person in Fresno: Salmon Technical Team, Salmon Advisory Subpanel, Ecosystem Advisory Subpanel, Ecosystem Workgroup, Enforcement Consultants, Habitat Committee, Groundfish Management Team, Groundfish Advisory Subpanel, and the Scientific and Statistical Committee.

DATES: The Pacific Council Advisory Bodies will meet on Tuesday, March 5, 2024. The Pacific Council meeting General Session will begin on Wednesday, March 6, 2024, at 9 a.m. Pacific time, reconvening at 8 a.m. on Thursday, March 7 through Monday, March 11, 2024. All meetings are open to the public, except for a Closed Session held from 8 a.m. to 9 a.m., Wednesday, March 6, to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES:

Meeting address: Meetings of the Pacific Council and its advisory entities will be held at the Doubletree by Hilton Hotel Fresno Convention Center, 2233 Ventura Street, Fresno, CA; telephone: (559) 268-1000. Specific meeting information, including directions on joining the meeting, connecting to the live stream broadcast, and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt

(kris.kleinschmidt@noaa.gov) or contact him at (503) 820-2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Mr. Merrick Burden, Executive Director, Pacific Council; telephone: (503) 820-2418 or (866) 806-7204 toll-free, or access the Pacific Council website, www.pcouncil.org, for the proposed agenda and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The March 6–11, 2024 meeting of the Pacific Council General Session will be streamed live on the internet. The broadcasts begin initially at 9 a.m. PT Wednesday, March 6, and 8 a.m. Thursday, March 7 through Monday, March 11, 2024. Broadcasts end when business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion for the public is listen-only except that an opportunity for oral public comment will be provided prior to Council Action on each agenda item. Additional information and instructions on joining or listening to the meeting can be found on the Pacific Council's website (see www.pcouncil.org).

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as "Final Action" refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, and advisory entity meeting times, are described in Agenda Item A.3, Proposed Council Meeting Agenda, and will be in the advance March 2024 briefing materials and posted on the Pacific Council website at www.pcouncil.org no later than Tuesday, February 13, 2024.

A. Call to Order

1. Opening Remarks
2. Roll Call
3. Agenda
4. Executive Director's Report

B. Open Comment Period

1. Comments on Non-Agenda Items

C. Salmon Management

1. National Marine Fisheries Service Report
2. Review of 2023 Fisheries and Summary of 2024 Stock Forecasts
3. Klamath Dam Removal Update
4. Klamath River Fall Chinook Workgroup Report and 2024

Management Options—Final Guidance

5. Identify Management Objectives and Preliminary Definition of 2024 Management Alternatives
6. Recommendations for 2024 Management Alternative Analysis
7. Further Direction for 2024 Management Alternatives
8. Further Direction for 2024 Management Alternatives
9. Adopt 2024 Management Alternatives for Public Review
10. Appoint Salmon Hearing Officers

D. Habitat Issues

1. Current Habitat Issues

E. Cross Fishery Management Plan (FMP)

1. Council and Scientific and Statistical Committee Discussion
 2. Office of National Marine Sanctuaries Coral Restoration and Research Plan—Range of Alternatives and Preliminary Preferred Alternative
 3. Marine Planning
- #### F. Groundfish Management
1. National Marine Fisheries Service Report and Electronic Monitoring Update
 2. Consideration of Additional California Quillback Rockfish Analyses and Adopt Rebuilding Analysis
 3. Initial Stock Assessment Plan and Terms of Reference
 4. Trawl Cost Recovery Annual Report
 5. Implementation of the 2024 Pacific Whiting Fishery under the U.S./Canada Agreement
 6. Fixed Gear Marking and Entanglement Risk Reduction—Preliminary Preferred Alternative
 7. 2025–26 Fisheries Analysis Update and Adopt California Quillback Rockfish Harvest Specifications and Rebuilding Parameters
 8. Inseason Adjustments—Final Action

G. Pacific Halibut Management

1. International Pacific Halibut Commission (IPHC) Report
2. Incidental Catch Recommendations: Options for Salmon Troll and Final Action for Fixed Gear Sablefish Fisheries

H. Ecosystem Management

1. California Current Ecosystem Status Report
2. Fishery Ecosystem Plan Initiative 4—Progress Review
3. Climate and Communities Initiative Review and Prioritize Tasks

I. Highly Migratory Species Management

1. National Marine Fisheries Service Report
2. International Management Activities
3. Highly Migratory Species Roadmap

- Workshop—Final Planning
- J. *Administrative Matters*
1. Approve Council Meeting Record
 2. Membership Appointments and Council Operating Procedures
 3. Future Council Meeting Agenda and Workload Planning

Advisory Body Agendas

Advisory body agendas will include discussions of relevant issues that are on the Pacific Council agenda for this meeting and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website, www.pcouncil.org, no later than Tuesday, February 13, 2024.

Schedule of Ancillary Meetings

Day 1—Tuesday, March 5, 2024

Habitat Committee 8 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Scientific and Statistical Committee 8 a.m.
 Enforcement Consultants 9 a.m.

Day 2—Wednesday, March 6, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Groundfish Management Team 8 a.m.
 Habitat Committee 8 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Scientific and Statistical Committee 8 a.m.
 Enforcement Consultants As Necessary

Day 3—Thursday, March 7, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Ecosystem Advisory Subpanel 8 a.m.
 Ecosystem Workgroup 8 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Groundfish Management Team 8 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Enforcement Consultants As Necessary

Day 4—Friday, March 8, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Ecosystem Advisory Subpanel 8 a.m.
 Ecosystem Workgroup 8 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Groundfish Management Team 8 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Enforcement Consultants As Necessary

Day 5—Saturday, March 9, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.

Washington State Delegation 7 a.m.
 Groundfish Advisory Subpanel 8 a.m.
 Groundfish Management Team 8 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Enforcement Consultants As Necessary

Day 6—Sunday, March 10, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Salmon Advisory Subpanel 8 a.m.
 Salmon Technical Team 8 a.m.
 Enforcement Consultants As Necessary

Day 7—Monday, March 11, 2024

California State Delegation 7 a.m.
 Oregon State Delegation 7 a.m.
 Washington State Delegation 7 a.m.
 Salmon Technical Team 8 a.m.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820-2412) at least 10 business days prior to the meeting date.
Authority: 6 U.S.C. 1801 *et seq.*

Dated: February 13, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-03304 Filed 2-15-24; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: March 17, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R.

Jurkowski, Telephone: (703) 785-6404, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):

4020-01-625-5683—Bungee Rope, Flexible, w/Crimped Loops, 3 feet, Tan
 4020-01-625-7190—Bungee Rope, Flexible, w/Crimped Loops, 3 feet, Black
 4020-01-625-7196—Bungee Rope, Flexible, w/Crimped Loops, 5 feet, Black
 4020-01-625-7203—Bungee Rope, Flexible, w/Crimped Loops, 3 feet, Camouflage
 4020-01-625-7215—Bungee Rope, Flexible, w/Crimped Loops, 3 feet, Olive Drab
 4020-01-625-8398—Bungee Rope, Flexible, w/Crimped Loops, 3 feet, Orange
 4020-01-625-8403—Bungee Rope, Flexible, w/Crimped Loops, 5 feet, Camouflage
 4020-01-625-8417—Bungee Rope, Flexible, w/Crimped Loops, 5 feet, Olive Drab
 4020-01-625-8430—Bungee Rope, Flexible, w/Crimped Loops, 5 feet, Orange
 4020-01-625-8441—Bungee Rope, Flexible, w/Crimped Loops, 5 feet, Tan
Designated Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA
 NSN(s)—Product Name(s):
 7530-01-156-9775—Paper, Xerographic, Dual Purpose, 3-Hole Punched, Blue, 8.5" x 11"

Designated Source of Supply: Louisiana Association for the Blind, Shreveport, LA

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):

6550-00-NIB-0023—Test Cup, Drug Detection, Round, 2-7/8" D x 3-1/2" H, 13-panel dipcard
Designated Source of Supply: Tarrant County Association for the Blind, Fort Worth, TX
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s):

7510-00-582-4201—Binder, Loose-leaf, Report Cover, Pressboard, 3" Capacity, Earth Red, 11" x 8-1/2"

7510-00-281-4309—Binder, Loose-leaf, Report Cover, Pressboard, 3" Capacity, Earth Red, 8-1/2" x 11"

7510-00-281-4310—Binder, Loose-leaf, Report Cover, Pressboard, 3" Capacity, Earth Red, 11" x 17"

7510-00-281-4313—Binder, Loose-leaf, Report Cover, Pressboard, 6" Capacity, Earth Red, 11" x 8-1/2"

7510-00-281-4314—Binder, Loose-leaf, Report Cover, Pressboard, 3" Capacity, Earth Red, 8-1/2" x 14"

7510-00-286-7794—Binder, Loose-leaf, Report Cover, Pressboard, No Fastener, 3" Capacity, Earth Red, 8-1/2" x 11"

Designated Source of Supply: Georgia Industries for the Blind, Bainbridge, GA

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):

7510-01-357-6829—Pad, Executive Message Recording, White/Yellow, 2-5/8" x 6-1/4", 200 Message Forms

Designated Source of Supply: VisionCorps, Lancaster, PA

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):

MR 11049—Bag, Tote, Reusable, Collapsible, Summer

MR 11096—Bag, Tote, Reusable, Collapsible, Christmas

MR 11086—Bag, Tote, Reusable, Collapsible, Halloween

MR 11122—Bag, Laminated, Large, Fresh Time

MR 11123—Bag, Laminated, Large, Menu

MR 11124—Bag, Laminated, Large, Baking

MR 11125—Bag, Laminated, Large, Grill

Meat

MR 11126—Bag, Tote, Reusable,

Collapsible, Everyday

MR 11127—Bag, Laminated, Large, Earth

Day

MR 11131—Reusable Shopping Bag,

Veterans' Day

MR 11133—Bag, Large, Laminated, U.S.A.

Flag and Fireworks

MR 11134—Bag, Large, Laminated, U.S.A.

Flag

MR 11135—Bag, Collapsible, Flags with

Poles

MR 11137—Bag, Gift, Valentine's Day, Two

Hearts With Love

MR 11138—Bag, Gift, Valentine's Day,

Cube, Hearts

MR 11139—Bag, Laminated, Large,

Hanukkah, Menorah

MR 11140—Bag, Cube, Hanukkah,

Menorah

MR 11141—Bag, Gift, Birthday

MR 11142—Bag, Laminated, Large,

Birthday Cake

MR 11143—Bag, Collapsible, Birthday

Balloons

MR 11091—Bag, Laminated, Large, Easter

Design 1

MR 11092—Bag, Laminated, Large, Easter

Design 2

MR 11093—Bag, Tote, Reusable,

Collapsible, Easter

MR 11094—Bag, Reusable, Laminated Gift

Size, Easter Design 1

MR 11095—Bag, Reusable, Laminated Gift

Size, Easter Design 2

MR 13067—Container, Clip Top, Ice Pack, Assorted Colors

MR 13068—Container, Multi-Pack,

Assorted Colors

MR 13069—Container, Noodles, Assorted

Colors

MR 13070—Mug, Soup, 24 oz, Assorted

Colors

MR 13071—Mug, Thermal, Assorted Colors

MR 13072—Container, Snap Top, Assorted

Colors

Designated Source of Supply: West Texas Lighthouse for the Blind, San Angelo, TX

Contracting Activity: MILITARY RESALE-

DEFENSE COMMISSARY AGENCY

NSN(s)—Product Name(s):

MR 11133—Bag, Large, Laminated, U.S.A.

Flag and Fireworks

Designated Source of Supply: Winston-Salem

Industries for the Blind, Inc., Winston-

Salem, NC

Contracting Activity: MILITARY RESALE-

DEFENSE COMMISSARY AGENCY

NSN(s)—Product Name(s):

MR 1177—Refill, Mop, Sticky

MR 587—Dual Action Dish Wand Refill

MR 924—Mop, Block Sponge w/Scrubber

Strip

MR 934—Refill, MR 924 Block w/Scrubber

MR 1057—Butterfly Mop, Hybrid Sponge

MR 1058—Refill, Hybrid Sponge Head,

Blue

Designated Source of Supply: LC Industries,

Inc., Durham, NC

Contracting Activity: MILITARY RESALE-

DEFENSE COMMISSARY AGENCY

NSN(s)—Product Name(s):

MR 533—SKILCRAFT Bio Serve Flatware

Designated Source of Supply: LC Industries,

Inc., Durham, NC

Contracting Activity: DEFENSE

COMMISSARY AGENCY, FORT

GREGG-ADAMS, VA

Michael R. Jurkowski, Acting Director, Business Operations.

[FR Doc. 2024-03275 Filed 2-15-24; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) from

the Procurement List previously furnished by such agencies.

DATES: Date added to and deleted from the Procurement List: March 17, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785-6404 or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 1/12/2024, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51-2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service(s) to the Government.

2. The action will result in authorizing small entities to furnish the service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Custodial & Grounds Maintenance

Mandatory for: Defense Contract Management Agency, Hancock Field Air National Guard Base, Building 613, Syracuse, NY

Designated Source of Supply: Oswego Industries, Inc., Fulton, NY

Contracting Activity: DEFENSE CONTRACT MANAGEMENT AGENCY (DCMA), DEFENSE CONTRACT MANAGEMENT OFFICE

Deletions

On 1/12/2024, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):

7530–01–516–7577—Pad, Writing Paper, Glue Bound Top, Legal Rule, White, 8– $\frac{1}{2}$ " x 13– $\frac{1}{4}$ "

7530–01–516–7572—Pad, Writing Paper, Glue Bound Top, Legal Rule, Canary, 5" x 8"

Designated Source of Supply: Blind Industries & Services of Maryland, Baltimore, MD

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):

3030–01–375–8087—Belt, Micro-V, V-ribbed, 4 Ribs, EPDM Rubber, 35.5" long
3030–01–466–9476—Belt, V-shaped, Micro, EPDM Rubber, 8 Ribs, 98.07"

Designated Source of Supply: Northeastern Association of the Blind at Albany, Inc., Albany, NY

Contracting Activity: DLA LAND AND MARITIME, COLUMBUS, OH

NSN(s)—Product Name(s): 8445–01–436–2695—Belt, Trousers, Women's, Type XII, Black, Size 45

Designated Source of Supply: Travis Association for the Blind, Austin, TX
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s): 8140–00–NSH–0014—Tube, Cardboard, Grenade, 155mm Projectile

Designated Source of Supply: SVRC Industries, Inc., Saginaw, MI
Contracting Activity: W4MM USA JOINT MUNITIONS CMD, ROCK ISLAND, IL

Service(s)

Service Type: Document Destruction
Mandatory for: VA Medical Clinic: 25 North Spruce, NULL, Colorado Springs, CO

Designated Source of Supply: Bayaud Enterprises, Inc., Denver, CO
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 259–NETWORK CONTRACT OFFICE 19

Service Type: Document Destruction
Mandatory for: Department of Veterans Affairs, Network Contracting Office, NCO 19, Glendale, CO

Designated Source of Supply: Bayaud Enterprises, Inc., Denver, CO
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 259–NETWORK CONTRACT OFFICE 19

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2024–03276 Filed 2–15–24; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Global Markets Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on March 6, 2024 from 10:00 a.m. to 3:00 p.m. Eastern Standard Time, the Global Markets Advisory Committee (GMAC) will hold an in-person public meeting at the CFTC's Washington, DC headquarters with options for the public to attend virtually. At this meeting, the GMAC will hear a presentation from the GMAC's Global Market Structure Subcommittee, Technical Issues Subcommittee, and Digital Asset Markets Subcommittee on various workstreams, and consider recommendations from the Subcommittees on such workstreams.

DATES: The meeting will be held on March 6, 2024, from 10:00 a.m. to 3:00 p.m. Eastern Standard Time. Please note that the meeting may end early if the GMAC has completed its business. Members of the public who wish to

submit written statements in connection with the meeting should submit them by March 13, 2024.

ADDRESSES: The meeting will take place in the Conference Center at the CFTC's headquarters, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. You may submit public comments, identified by "Global Markets Advisory Committee," through the CFTC website at <https://comments.cftc.gov>. Follow the instructions for submitting comments through the Comments Online process on the website. If you are unable to submit comments online, contact Harry Jung, Designated Federal Officer, via the contact information listed below to discuss alternate means of submitting your comments. Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC website, <https://www.cftc.gov>.

FOR FURTHER INFORMATION CONTACT:

Harry Jung, Global Markets Advisory Committee Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC; (202) 394–3995; or HJung@cftc.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public with seating on a first-come, first-served basis. Members of the public may also listen to the meeting by telephone by calling a domestic or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

Domestic Toll and Toll-Free Numbers:

+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 646 964 1167 US (US Spanish Line)
+1 669 216 1590 US (San Jose)
+1 415 449 4000 US (US Spanish Line)
+1 551 285 1373 US (New Jersey)
833 435 1820 US Toll Free
833 568 8864 US Toll Free

International Numbers are available here: <https://cftc.gov.zoomgov.com/join/9111111111>, and will be posted on the CFTC's website, <https://www.cftc.gov>, on the page for the meeting, under Related Links.

Call-In/Webinar ID: 161 691 1228

Pass Code/Pin Code: 129163

Members of the public may also view a live webcast of the meeting via the <https://www.cftc.gov> website. The meeting agenda may change to accommodate other Committee priorities. For agenda updates, please visit <https://www.cftc.gov/About/AdvisoryCommittees/GMAC>.

After the meeting, a transcript of the meeting will be published through a link on the CFTC's website, <https://www.cftc.gov>. Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

(Authority: 5 U.S.C. 1009(a)(2).)

Dated: February 13, 2024.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2024-03266 Filed 2-15-24; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES: DACOWITS will hold an open to the public meeting—Tuesday, March 19, 2024, from 8:00 a.m. to 2:15 p.m. (EST).

ADDRESSES: The meeting will take place at the Association of the United States Army Conference Center, located at 2425 Wilson Boulevard, Arlington, Virginia, 22201. The meeting will also be held virtually. To participate in the meeting, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: LTC Samantha Frazier, Designated Federal Officer (DFO), (202) 650-2943 (voice), Samantha.j.frazier11.mil@mail.mil (email). The most up-to-date changes to the meeting agenda can be found on the website: <https://dacowits.defense.gov>.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the “Federal Advisory Committee Act” or “FACA”), 5 U.S.C. 552b (commonly known as the “Government in the Sunshine Act”), and 41 Code of Federal Regulations (CFR) 102-3.140 and 102-3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available at the DACOWITS website, <https://dacowits.defense.gov/>.

Materials presented in the meeting may also be obtained on the DACOWITS website.

Purpose of the Meeting: The purpose of the meeting is for the DACOWITS to receive briefings and have discussions on topics related to the recruitment, retention, employment, integration, well-being, and treatment of women in the Armed Forces of the United States.

Agenda: Tuesday, March 19, 2024, from 8:00 a.m. to 2:15 p.m.—Welcome, Introductions, Announcements, Request for Information Status Update, Briefings, Public Comment Period, and DACOWITS discussion.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102-3.140 through 102-3.165, this meeting is open to the public, subject to availability of space, from 8:00 a.m. to 2:15 p.m. on March 19, 2024. The meeting will also be streamed by videoconference. The number of participants is limited and is on a first-come basis. Any member of the public who wishes to participate via videoconference must register by contacting DACOWITS at osd.pentagon.ousd-p-r.mbx.dacowits@mail.mil or by contacting Mr. Robert Bowling at (703) 380-0116 no later than Monday, March 11, 2024. Once registered, the videoconference information will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Robert Bowling no later than Monday, March 11, 2024, so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102-3.140, and section 10(a)(3) of the FACA, interested persons may submit a written statement to the DACOWITS. Individuals submitting a written statement must submit their statement no later than 5:00 p.m., Monday, March 11, 2024, to Mr. Robert Bowling (703) 380-0116 (voice) or to robert.d.bowling1.civ@mail.mil (email). Mailing address is 4800 Mark Center Drive, Suite 06E22, Alexandria, VA 22350. Members of the public interested in making an oral statement, must submit a written statement. If a statement is not received by Monday, March 11, 2024, it may not be provided to or considered by the Committee during this quarterly business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting persons are permitted to make an oral presentation. The DFO will review all timely submissions with the DACOWITS Chair and ensure they are provided to the members of the Committee.

Dated: February 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-03291 Filed 2-15-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2024-SCC-0027]

Agency Information Collection Activities; Comment Request; Personal Authentication Service (PAS) for Federal Student Aid ID

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before APRIL 16, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2024-SCC-0027. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the [regulations.gov](http://www.regulations.gov) site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Personal Authentication Service (PAS) for FSA ID.

OMB Control Number: 1845–0131.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 6,671,000..

Total Estimated Number of Annual Burden Hours: 1,667,750.

Abstract: Federal Student Aid (FSA) requests extension without change of the Person Authentication Service (PAS) which creates an FSA ID, a standard username and password solution. In order to create an FSA ID to gain access to certain FSA systems (the Free Application for Federal Student Aid (FAFSA) on the Web, National Student Loan Data System (NSLDS), *StudentLoans.gov*, etc.) a user must register on-line for an FSA ID account. The FSA ID allows the customer to have a single identity, even if there is a name change or change to other personally identifiable information. The information collected to create the FSA ID enables electronic authentication and authorization of users for FSA web-based applications and information and protects users from unauthorized access to user accounts on all protected FSA sites.

Dated: February 13, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–03259 Filed 2–15–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0028]

Agency Information Collection Activities; Comment Request; Safer Schools and Campuses Best Practices Clearinghouse

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before April 16, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2023–SCC–0028. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Victoria Hammer, 202–260–1438.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Safer Schools and Campuses Best Practices Clearinghouse.

OMB Control Number: 1810–0753.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 300.

Total Estimated Number of Annual Burden Hours: 450.

Abstract: This is a request for approval of an extension without change of the OMB approved collection, 1810–0753 Safer Schools and Campuses Best Practices Clearinghouse. The U.S. Department of Education (Department) collects lessons learned and best practices from the field to populate the Safer Schools and Campuses Best Practices Clearinghouse (Clearinghouse) in response to the directive to do so in Executive Order 14000 issued on January 21, 2021, by the President. This extension will allow the Department to continue collecting lessons learned and best practices for the Clearinghouse.

The purpose for this collection is to ensure that the Department has sufficient information to review and, if appropriate, approve submissions to include in the Clearinghouse.

Dated: February 13, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024-03274 Filed 2-15-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Applications for New Awards; Training Program for Federal TRIO Programs

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for new awards for fiscal year (FY) 2024 for the Training Program for Federal TRIO Programs (Training Program), Assistance Listing Number 84.103A. This notice relates to the approved information collection under OMB control number 1840-0814.

DATES:

Applications Available: February 16, 2024.

Deadline for Transmittal of Applications: April 16, 2024.

Deadline for Intergovernmental Review: June 17, 2024.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at www.federalregister.gov/d/2021-27979. Please note that these Common Instructions supersede the version published on December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Suzanne Ulmer, U.S. Department of Education, 400 Maryland Avenue SW, 5th floor, Washington, DC 20202-4260. Telephone: (202) 453-7691. Email: Suzanne.Ulmer@ed.gov; or ReShone Moore, Ph.D., U.S. Department of Education, 400 Maryland Avenue SW, 5th floor, Washington, DC 20202-4260. Telephone: (202) 453-7624. Email: reshone.moore@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7-1-1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Training Program provides grants to train the

staff and leadership personnel employed in, participating in, or preparing for employment in, projects funded under the Federal TRIO Programs, to improve project operation.

Priorities: This notice contains six absolute priorities and one invitational priority. In accordance with 34 CFR 75.105(b)(2)(iv) and 34 CFR 75.105(b)(2)(ii), the absolute priorities are from section 402G(b) of the Higher Education Act of 1965, as amended (HEA), and the regulations for this program at 34 CFR 642.24. The invitational priority is intended to address mental health challenges faced by project directors and employees of TRIO projects by providing training and informational resources to support their mental health.

Absolute Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet one of these absolute priorities.

In accordance with 34 CFR 642.7, each application must clearly identify the specific absolute priority for which a grant is requested. An applicant must submit a separate application for each absolute priority it proposes to address. If an applicant submits more than one application for the same absolute priority, we will accept only the application with the latest “date/time received” validation.

These priorities are:

Absolute Priority 1: Training to improve reporting of student and project performance and project evaluation, in order to design and operate a model program for projects funded under the Federal TRIO Programs.

Absolute Priority 2: Training on budget management and the statutory and regulatory requirements for the operation of projects funded under the Federal TRIO Programs.

Absolute Priority 3: Training on assessment of student needs; retention and graduation strategies; and the use of appropriate educational technology in the operation of projects funded under the Federal TRIO programs.

Absolute Priority 4: Training on assisting students in receiving adequate financial aid from programs assisted under title IV of the HEA and from other programs, and on college and university admissions policies and procedures.

Absolute Priority 5: Training on strategies for recruiting and serving hard to reach populations, including students who are limited English proficient, students from groups that are traditionally underrepresented in

postsecondary education, students with disabilities, students who are homeless children and youths (as this term is defined in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a)), students who are foster care youth, or other disconnected students.

Absolute Priority 6: Training on general project management for new project directors.

Invitational Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

Background: According to the Occupational Safety and Health Administration (OSHA), stress can be harmful to our health and increase mental health challenges.¹ While there are many things in life that induce stress, work can be one of those factors. The World Health Organization reported in 2022 that 83 percent of U.S. workers suffer from work-related stress and 54 percent of workers report that work stress affects their home life.² Studies indicate the COVID-19 pandemic exacerbated the issue.³

The workplace can be a key place for resources, solutions, and activities designed to improve mental health and well-being.⁴ The TRIO workplace provides an opportunity to provide needed supports and resources. Through this invitational priority, the Department encourages applicants to provide critical support to assist TRIO staff.

Priority:

Training on mental health supports for TRIO project directors and staff.

Program Authority: 20 U.S.C. 1070a-11 and 1070a-17.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

¹ Occupational Safety and Health Administration, (2024). Workplace stress: Understanding the problem. Retrieved from: www.osha.gov/workplace-stress

² The World Health Organization (2022). [who.int/teams/mental-health-and-substance-use/promotion-prevention/mental-health-in-the-workplace](https://www.who.int/teams/mental-health-and-substance-use/promotion-prevention/mental-health-in-the-workplace)

³ Gramlich, John, (2023). Mental health and the pandemic: What U.S. surveys have found. Retrieved from: www.pewresearch.org/short-reads/2023/03/02/mental-health-and-the-pandemic-what-u-s-surveys-have-found/

⁴ Occupational Safety and Health Administration, (2024). Workplace stress: Understanding the problem. Retrieved from: www.osha.gov/workplace-stress

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75 (except for 75.215 through 75.221), 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 642.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested \$1,297,761,000 for the Federal TRIO Programs for FY 2024, of which we intend to use an estimated \$4,377,536 for the Training Program for Federal TRIO Programs. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for the Federal TRIO Programs.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: \$309,505–\$402,357, depending on the absolute priority under which the award is funded (see below).

Estimated Average Size of Awards: \$355,931.

Maximum Award and Minimum Participants: We will not make an award exceeding the maximum award amount listed here for a single budget period of 12 months. Projects proposed under each absolute priority also must propose to serve the minimum number of applicable participants listed here.

Under Absolute Priorities 1, 2, and 4, the maximum award amount is \$309,505 and the minimum number of participants is 231. Under Absolute Priorities 3 and 5, the maximum award amount is \$402,357 and the minimum number of participants is 300. Under Absolute Priority 6, the maximum award amount is \$343,159 and the minimum number of participants is 256.

Estimated Number of Awards: 13, as follows: 2 awards each under Absolute Priorities 1, 2, 3, 5, and 6; and 3 awards under Absolute Priority 4.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs and other public and private nonprofit institutions and organizations.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see www2.ed.gov/about/offices/list/ocfo/intro.html.

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at www.federalregister.gov/d/2022-26554, which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on December 27, 2021.

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

3. *Funding Restrictions:* We specify unallowable costs in 34 CFR 642.31. We reference additional regulations outlining funding restrictions in the *Applicable Regulations* and *Application Review Information* sections of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative, which includes the budget narrative and invitational priority, if addressed, to no more than 55 pages and (2) use the following standards:

- A “page” is 8.5” × 11”, on one side only, with 1” margins.
- Double space all text in the application narrative, and single space titles, headings, footnotes, quotations, references, and captions.
- Use a 12-point font.
- Use an easily readable font such as Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the Application for Federal Assistance face sheet (SF 424); Part II, the Budget Information Summary form (ED Form 524); Part III–A, the Program Profile form; Part III–B, the one-page Project Abstract form; or Part IV, the Assurances and Certifications. The recommended page limit also does not apply to a table of contents, which we recommend that you include in the application narrative.

5. *Content and Form of Application Submission:* You must indicate the absolute priority addressed in your application both on the one-page abstract and on the Training Program Profile Sheet. You must include your complete response to the selection criteria and absolute priority in the application narrative. Other requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 642.21 and 34 CFR 75.210. The points assigned to each criterion are indicated in the parentheses next to the criterion. An applicant may earn up to a total of 100 points based on the selection criteria for the application.

(a) *Plan of operation.* (20 points)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that ensures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective; and

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Individuals with disabilities; and

(D) The elderly.

(b) *Quality of key personnel.* (20 points)

(1) The Secretary reviews each application for information that shows the qualifications of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(2)(i) and (ii) of this section plans to commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Individuals with disabilities; and

(D) The elderly.

(3) To determine the qualifications of a person, the Secretary considers evidence of past experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (10 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan.* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources.* (15 points)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(f) *Quality of the project design.* (10 points)

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the extent to which the proposed project represents an exceptional approach for meeting statutory purposes and requirements.

(g) *Quality of project services.* (15 points)

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the extent to which the technical assistance services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

Note: For Selection Criterion (b), Quality of key personnel, applicants are encouraged to include in their application that they are committed to paying their trainers a living wage for the local area and providing benefits.

2. *Review and Selection Process:* We remind potential applicants that in

reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

For this competition, a panel of non-Federal reviewers will review each application in accordance with the selection criteria in 34 CFR 642.21 and 34 CFR 75.210. The individual scores of the reviewers will be added and the sum divided by the number of reviewers to determine the peer review score received in the review process.

Additionally, in accordance with 34 CFR 642.22, the Secretary will award up to 15 prior experience points to eligible applicants by evaluating the applicant's current performance under its expiring Training Program grant. Pursuant to 34 CFR 642.20(d), if there are insufficient funds to fund all applications with the same peer review score within a particular absolute priority, prior experience points, if any, will be added to the averaged peer review score to determine the total score for each application.

Under section 402A(c)(3) of the HEA, the Secretary is not required to make awards under the Training Program in the order of the scores received.

Additionally, under 34 CFR 642.23, the Secretary, to the greatest extent possible, makes Training Program awards to projects that will provide training services in all regions of the Nation in order to assure accessibility for prospective training participants, in accordance with the criteria described below.

In the event a tie score still exists after applying prior experience points, the Secretary will select for funding the applicant that has the greatest capacity to provide training to eligible participants in all regions of the Nation, in order to assure accessibility to the greatest number of prospective training participants, consistent with 34 CFR 642.20(e). If it is determined that all tied applicants have equal capacity to provide training to eligible participants

in all regions of the Nation, the Secretary will identify and recommend an award for—

First, the applicant in the funding band that is from an entity receiving the least amount of funding under any of the other absolute priorities.

Second, the applicant with the highest average score across all applications.

Third, if there is more than one application with the same score and insufficient funding to support these applications after tie-breaker 1 and tie-breaker 2 have been implemented, the applicant proposing to serve the greatest number of participants through both their on-site and online trainings will be the final application identified and recommended to receive an award.

3. Risk Assessment and Specific Conditions: Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. Integrity and Performance System: If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, appendix XII, require you to report certain integrity information to FAPIS semiannually. Please review the requirements in 2 CFR

part 200, appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

5. In General: In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. Award Notices: If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we will notify you.

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Open Licensing Requirements: Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing

works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. Reporting:(a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

5. Performance Measures: For purposes of Department reporting under 34 CFR 75.110, the Department will use the following performance measures to assess the effectiveness and quality of the Training Program:

(1) Its cost-effectiveness based on the number of TRIO project personnel receiving training each year;

(2) The percentage of Training Program participants that, each year, indicate the training has increased their qualifications and skills in meeting the needs of disadvantaged students; and

(3) The percentage of Training Program participants that, each year, indicate the training has increased their knowledge and understanding of the Federal TRIO Programs. All grantees will be required to include in their annual performance report project data documenting their success in training personnel working on TRIO-funded projects, including the average cost per trainee and the trainees' evaluations of the effectiveness of the training provided. The success of the Training Program also is assessed on the

quantitative and qualitative outcomes of the training projects based on project evaluation results.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Nasser H. Paydar,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2024-03277 Filed 2-15-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2024-SCC-0026]

Agency Information Collection Activities; Comment Request; PLUS Adverse Credit Reconsideration Loan Counseling

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before April 16, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2024-SCC-0026. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377-4018.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: PLUS Adverse Credit Reconsideration Loan Counseling.

OMB Control Number: 1845-0129.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Individuals or Households *Total Estimated Number of Annual Responses:* 142,824.

Total Estimated Number of Annual Burden Hours: 107,119.

Abstract: Section 428B(a)(1)(A) of the Higher Education Act of 1965, as amended (HEA), provides that to be eligible to receive a Federal PLUS Loan under the Federal Family Education Loan (FFEL) Program, the applicant must not have an adverse credit history, as determined pursuant to regulations promulgated by the Secretary. In accordance with section 455(a)(1) of the HEA, this same eligibility requirement applies to applicants for PLUS loans under the Direct Loan Program. Since July 1, 2010, there have been no new FFEL Program loans originated and the Direct Loan Program is the only Federal loan program that offers Federal PLUS Loans.

The adverse credit history section of the eligibility regulations in 34 CFR 685.200(b) and (c) were updated in 2014 by the Department of Education (the Department) when a review of and a change to the regulations was made.

Specifically, an applicant for a PLUS loan who is determined to have an adverse credit history must complete loan counseling offered by the Secretary before receiving the Federal PLUS loan.

The Department is requesting an extension to the information collection regarding the adverse credit history regulations in 34 CFR 685.200 (b) and (c) and the burden these changes create for Federal PLUS loan borrowers, both parent and graduate/professional students.

Dated: February 13, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024-03230 Filed 2-15-24; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

National Definition for a Zero Emissions Building: Part 1 Operating Emissions Version 1.00m Draft Criteria; Reopening of Public Comment Period

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information; reopening of public comment period.

SUMMARY: On January 9, 2024, the U.S. Department of Energy (DOE) published in the **Federal Register** a Request for Information (RFI) regarding the creation of a standardized, verifiable basis for defining a zero emissions building by the White House Office of Domestic Climate Policy (Climate Policy Office), through DOE. The RFI provided for the submission of written comments by February 5, 2024. This notice announces a reopening of the public comment period for submitting comments in response to the RFI through March 6, 2024.

DATES: The comment period for the RFI published on January 9, 2024 (89 FR 1086) is reopened. DOE will accept comments, data, and information regarding this RFI received no later than March 6, 2024.

ADDRESSES: Responses to this RFI must be submitted electronically at <https://forms.office.com/g/Y0Ss3UFdL3>.

FOR FURTHER INFORMATION CONTACT: Hayes Jones, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy (EERE), Building Technologies Office, Commercial

Buildings Integration, (202) 586-8873, Hayes.Jones@ee.doe.gov.

SUPPLEMENTARY INFORMATION: On January 9, 2024, DOE published in the **Federal Register** a request for information (RFI) regarding the creation of a standardized, verifiable basis for defining a zero emissions building by the Climate Policy Office, through DOE. The RFI does not pertain to a rulemaking action. In addition to other net-zero emissions, economy-wide goals by 2050, within the building sector, the Biden-Harris Administration has set the goal to make zero emissions resilient new construction and retrofits comment practice by 2030. Accomplishing these goals will require increasing efficiency and expanding clean energy capacity. Zero emissions buildings will plug into a grid that is rapidly becoming cleaner.

The American Gas Association, American Public Gas Association, and National Propane Gas Association ("Joint Requesters") have requested a 30-day extension of the comment period to allow additional time for preparation of their comments. The Joint Requesters explain that they provide the energy needed to fuel residential, commercial, and industrial buildings and are thus stakeholders in this proceeding. The Joint Requesters explained that they need additional time to develop comments that sufficiently analyze the impacts of the proposed definition and because limited staff available during the comment period would make it difficult to develop comments in response to the RFI. Similarly, the National Association of Home Builders requested an extension of the comment period because of staffing limitations and concerns over the definition for which they would like additional time to provide feedback.

DOE has determined that reopening the public comment period is appropriate based on the foregoing reasons. DOE will consider any comments received by 11:59 p.m. (Eastern Standard Time) of March 6, 2024, and deems any comments received by that time to be timely submitted.

Signing Authority

This document of the Department of Energy was signed on February 8, 2024, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal**

Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on February 13, 2024.

Treena V. Garrett,

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

[FR Doc. 2024-03285 Filed 2-15-24; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management (EM), Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, March 20, 2024; 1 p.m. to 5 p.m. MDT.

ADDRESSES: This hybrid meeting will be open to the public in person and via WebEx. To attend virtually, please contact the Northern New Mexico Citizens Advisory Board (NNMCAB) Executive Director (below) no later than 5 p.m. MDT on Friday, March 15, 2024.

Cities of Gold Hotel,
10-A Cities of Gold Road,
Santa Fe, New Mexico 87506

FOR FURTHER INFORMATION CONTACT: Bridget Maestas, NNMCAB Executive Director, by phone: 505-709-7466 or email: bridget.maestas@em.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda:

- Presentation on Groundwater Monitoring at Los Alamos National Laboratory
- Agency Updates

Public Participation: The in-person/online virtual hybrid meeting is open to the public in person or virtually, via WebEx. Written statements may be filed with the Board no later than 5 p.m. MDT on Friday, March 15, 2024, or within seven days after the meeting by sending them to the NNM CAB Executive Director at the aforementioned email address. Written public comments received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to submit public comments should follow the directions in this section.

Minutes: Minutes will be available by emailing or calling Bridget Maestas, NNM CAB Executive Director, at bridget.maestas@em.doe.gov or at (505) 709-7466.

Signing Authority: This document of the Department of Energy was signed on February 13, 2024, by David Borak, Deputy Committee Management Officer, 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 February 13, 2024.

Treena V. Garrett,

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

[FR Doc. 2024-03273 Filed 2-15-24; 8:45 am]

BILLING CODE 6450-01-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: EC24-50-000.

Applicants: GC PGR Holdco, LLC, PGR Holdco, LLC, Healthcare of Ontario Pension Plan Trust Fund.

Description: Application for Authorization Under Section 203 of the Federal Power Act of PGR Holdco, LLC.
Filed Date: 2/9/24.

Accession Number: 20240209-5226.

Comment Date: 5 p.m. ET 3/1/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1818-029.

Applicants: Public Service Company of Colorado.

Description: Amendment to March 11, 2023 Triennial Market Power Analysis for Southwest Region of Public Service Company of Colorado.

Filed Date: 2/9/24.

Accession Number: 20240209-5222.

Comment Date: 5 p.m. ET 3/1/24.

Docket Numbers: ER22-2185-001.

Applicants: Black Hills Colorado Electric, LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 2/12/24.

Accession Number: 20240212-5132.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1191-001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2024-02-12 Amendment to Forced-Off Assets Filing to be effective 6/3/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5097.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1230-000.

Applicants: Duke Energy Florida, LLC.

Description: Tariff Amendment: DEF-SEPA—Notice of Cancellation RS No. 65 to be effective 4/20/2024.

Filed Date: 2/9/24.

Accession Number: 20240209-5197.

Comment Date: 5 p.m. ET 3/1/24.

Docket Numbers: ER24-1231-000.

Applicants: Wythe County Solar Project, LLC.

Description: Baseline eTariff Filing: Market Based Rate to be effective 4/12/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5041.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1231-001.

Applicants: Wythe County Solar Project, LLC.

Description: Tariff Amendment: Market Based Rate to be effective 4/12/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5050.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1232-000.

Applicants: Midcontinent Independent System Operator, Inc., Consumers Energy Company, Michigan Electric Transmission Company, LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2024-02-12 SA 1926 METC-CE 10th Rev DTIA to be effective 2/1/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5058.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1233-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Substitute Original 4089 Sholes Wind II GIA to be effective 6/14/2023.

Filed Date: 2/12/24.

Accession Number: 20240212-5061.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1234-000.

Applicants: NorthWestern Corporation.

Description: § 205(d) Rate Filing: RS 27—Third Amended and Restated AMPS Agreement to be effective 1/12/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5063.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1235-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2024-02-12 Holy Cross DWA—Crystal Substation—698 to be effective 2/13/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5107.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1236-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2024-02-12 Holy Cross DWA—Parachute Substation—697 to be effective 2/13/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5109.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1237-000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2024-02-12 Holy Cross DWA—Rifle Substation—696 to be effective 2/13/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5110.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1238-000.

Applicants: ISO New England Inc., NSTAR Electric Company.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing

per 35.13(a)(2)(iii): ISO-NE/NSTAR; Original Service Agreement No. LGIA-ISON/NESTAR-23-04 to be effective 1/10/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5135.

Comment Date: 5 p.m. ET 3/4/24.

Docket Numbers: ER24-1239-000.

Applicants: Stanton Clean Energy, LLC.

Description: Baseline eTariff Filing: Stanton Cost-Based Power Purchase Agreement with OUC to be effective 4/1/2024.

Filed Date: 2/12/24.

Accession Number: 20240212-5141.

Comment Date: 5 p.m. ET 3/4/24.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: February 12, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-03319 Filed 2-15-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2601-077]

Northbrook Carolina Hydro II, LLC; Notice of Application for Surrender of License Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of License.

b. *Project No:* P-2601-077.

c. *Date Filed:* November 16, 2023.

d. *Applicant:* Northbrook Carolina Hydro II, LLC.

e. *Name of Project:* Bryson Hydroelectric Project.

f. *Location:* The project is located on the Oconaluftee River in Swain County, North Carolina. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Chuck Ahlrichs, 14550 N. Frank Lloyd Wright Blvd., Suite 210, Scottsdale, AZ 85260, (480) 551-1771, cahlrichs@nbenergy.com.

i. *FERC Contact:* Michael Calloway, (202) 502-8041, Michael.Calloway@ferc.gov.

j. *Cooperating agencies:* With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* March 13, 2024.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests 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 at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P-2601-077. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request:* Northbrook Carolina Hydro II, LLC (licensee) is proposing to surrender the project license. The project is located on the Oconaluftee River downstream of the Great Smoky Mountain National Park and the lands of the Eastern Band of Cherokee Indians (Qualla Boundary). The Project boundary abuts the Qualla Boundary for 1.5 miles. The proposed mode of surrender would include disconnection from the utility interconnection point and the removal of the generators and turbines. The licensee would offer the generators, control equipment, and wiring for sale following decommissioning, or would properly dispose of the equipment. The proposal includes leaving the dam and associated structures intact and operational. The licensee intends to later deed ownership of the project to Mainspring Conservation Land Trust for potential future removal of the dam after the surrender is final.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at <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. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances

related to this or other pending projects. For assistance, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene*: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents*: Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: February 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-03316 Filed 2-15-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24-52-000]

ANR Pipeline Company; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on January 31, 2024, ANR Pipeline Company (ANR), 700 Louisiana Street, Suite 1300, Houston, Texas 77002-2700, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA), and ANR's blanket certificate issued in Docket No. CP24-52-000, for authorization to abandon two injection/withdrawal wells, associated pipes, and appurtenances. All of the above facilities are located in Osceola County, Michigan (2024 Loreed Wells Abandonment Project). The project will allow ANR to abandon the two I/W wells in order to limit integrity risk in alignment with the guidance of the PHMSA Storage Final Rule. The estimated cost for the project is approximately \$966,000, 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 (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. Public access to records formerly available in the Commission's physical Public Reference Room, which was located at the Commission's headquarters, 888 First Street NE, Washington, DC 20426, are now available via the Commission's website. For assistance, contact the Federal Energy Regulatory Commission at FercOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or TTY (202) 502-8659.

Any questions concerning this request should be directed to David A. Alonzo, Manager, Project Authorizations, ANR

Pipeline Company, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas, 77002-2700, at (832) 320-5477 or 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 April 12, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² 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 April 12, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

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).

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 Procedure⁴ and the regulations under the NGA⁵ by the intervention deadline for the project, which is April 12, 2024. 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 April 12, 2024. 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 CP24-52-000 in your submission.

(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"; or⁶

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24-52-000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: David A. Alonzo, Manager, Project Authorizations, ANR Pipeline Company, LLC, 700 Louisiana Street, Suite 1300, Houston, TX 77002-2700, or by david_alonzo@tcenergy.com. 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

⁶ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

also provides access to the texts of all 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.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-03317 Filed 2-15-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24-396-000.
Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Revisions to Tariff—General and Housekeeping Matters to be effective 3/13/2024.

Filed Date: 2/12/24.
Accession Number: 20240212-5035.
Comment Date: 5 p.m. ET 2/26/24.

Docket Numbers: RP24-397-000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements (CML, ESS) to be effective 3/14/2024.

Filed Date: 2/12/24.
Accession Number: 20240212-5052.
Comment Date: 5 p.m. ET 2/26/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

⁴ 18 CFR 385.214.

⁵ 18 CFR 157.10.

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.

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Dated: February 12, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-03318 Filed 2-15-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP-OFA-111]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202-564-5632 or <https://www.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EIS) Filed February 5, 2024 10 a.m. EST Through February 12, 2024 10 a.m. EST Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

EIS No. 20240025, Draft, USAF, MA, Air National Guard F-15EX Eagle II and F-35A Lightning II Operational Beddowns, Comment Period Ends: 04/05/2024, Contact: Mr. Will Strickland 240-612-7042.

EIS No. 20240026, Final, FERC, WA, Goldendale Energy Storage Project, Review Period Ends: 03/18/2024, Contact: Office of External Affairs 866-208-3372.

EIS No. 20240027, Draft, NRC, SC, Site-Specific Environmental Impact Statement for Subsequent License

Renewal of Oconee Nuclear Station, Units 1, 2, and 3 Second Renewal, Draft Report for Comment, Comment Period Ends: 04/01/2024, Contact: Lance Rakovan 301-415-2589.

EIS No. 20240028, Draft, USFS, CA, Social and Ecological Resilience Across the Landscape 2.0 (SERAL 2.0), Comment Period Ends: 04/01/2024, Contact: Benjamin Cossel 209-288-6261.

Amended Notice: EIS No. 20240016, Final Supplement, FHWA, OR, Earthquake Ready Burnside Bridge, Contact: Thomas Parker 503-316-2549.

Correcting absence of supplemental text. Under 23 U.S.C. 139(n)(2), FHWA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

Dated: February 12, 2024.

Julie Smith,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024-03248 Filed 2-15-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[CERCLA-02-2024-2004; FRL-11701-01-R2]

Proposed CERCLA Cost Recovery Settlement for the Frankfort Asbestos Superfund Site, Frankfort, Herkimer County, New York

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, ("CERCLA"), notice is hereby given by the U.S. Environmental Protection Agency ("EPA"), Region 2, of a proposed cost recovery settlement agreement ("Settlement") pursuant to CERCLA with Jonathan Deck ("Settling Party") relating to the Frankfort Asbestos Superfund Site ("Site"), located in Frankfort, Herkimer County, New York.

DATES: Comments must be submitted on or before March 18, 2024.

ADDRESSES: Requests for copies of the proposed Settlement and submission of comments must be via electronic mail. Comments should reference the Frankfort Asbestos Superfund Site,

Frankfort, Herkimer County, New York, Index No. CERCLA-02-2024-2004. For those unable to communicate via electronic mail, please contact the EPA employee identified below.

FOR FURTHER INFORMATION CONTACT:

Jocelyn Scott, Attorney, Office of Regional Counsel, New York/Caribbean Superfund Branch, U.S. Environmental Protection Agency, 290 Broadway, 17th Floor, New York, NY 10007-1866.

Email: scott.jocelyn@epa.gov.

Telephone: 212-637-3179.

SUPPLEMENTARY INFORMATION: The Settling Party will pay to the United States \$110,000.00, of which \$82,650 is for past costs incurred by EPA at the Site, \$25,000 is for civil penalties for noncompliance with an administrative order, and an additional \$2,350 is for interest on the past cost amount. The Settlement includes a covenant by EPA not to sue or to take administrative action against the Settling Party pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a), with regard to EPA's past response costs as provided in the Settlement. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the proposed Settlement. EPA will consider all comments received and may modify or withdraw its consent to the proposed Settlement if comments received disclose facts or considerations that indicate that the proposed Settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 2, 290 Broadway, New York, New York 10007-1866.

Pasquale Evangelista,

Director, Superfund & Emergency Management Division, U.S. Environmental Protection Agency, Region 2.

[FR Doc. 2024-03309 Filed 2-15-24; 8:45 am]

BILLING CODE 6560-50-P

EXPORT-IMPORT BANK

Updated Intent To Conduct a Detailed Economic Impact Analysis

AGENCY: Export-Import Bank.

ACTION: Notice.

SUMMARY: This notice is to inform the public that the Export-Import Bank of the United States has received a request to increase the financed amount for a previously notified application (FR Doc. 2022-13827). The application is now for a \$743 million direct loan to support the export of approximately \$439 million worth of U.S. engineering services,

design services, licenses, catalysts, and refining equipment. The U.S. goods and services will be exported to Malaysia and establish production capacity of refined petrochemicals. There has been no significant change in the expected output of the facility, and the supported U.S. exports will enable the facility to produce 725 thousand metric tons per year of jet fuel, 894 thousand metric tons per year of light naphtha, 432 thousand metric tons per year of low sulfur fuel oil, 1.83 million metric tons per year of paraxylene, and 632 thousand metric tons per year of benzene. Production of paraxylene and benzene will primarily be sold to East Asia, while production of jet fuel, light naphtha, low sulfur fuel oil will primarily be sold regionally in Southeast Asia.

DATES: Comments are due 14 days from publication in the **Federal Register**.

ADDRESSES: Interested parties may submit comments on this transaction electronically on www.regulations.gov, or by email to economic.impact@exim.gov.

Scott Condren,

*Vice President, Policy Analysis Division,
Office of Policy Analysis and International
Relations.*

[FR Doc. 2024-03249 Filed 2-15-24; 8:45 am]

BILLING CODE 6690-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1257; FR ID 203006]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications
Commission.

ACTION: Notice and request for
comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize

the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before April 16, 2024. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060-1257.

Title: New Procedure for Non-Federal Public Safety Entities to License Federal Government Interoperability Channels.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Not-for-profit institutions and State, local, or tribal government.

Number of Respondents and Responses: 40,599 respondents; 40,599 responses.

Estimated Time per Response: 0.25 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Section 90.25 adopted in Order DA 18-282, requires any non-federal public safety entity seeking to license mobile and portable units on the Federal Interoperability Channels to obtain written concurrence from its Statewide Interoperability Coordinator (SWIC) or a state appointed official and include such written concurrence with its application for license. A non-federal public safety entity may communicate on designated Federal Interoperability Channels for joint federal/non-federal operations, provided it first obtains a license from the Commission authorizing use of the channels. Statutory authority for these collections are contained in 47 U.S.C.

151, 154, 301, 303, and 332 of the Communications Act of 1934.

Total Annual Burden: 10,150 hours.

Total Annual Cost: No cost.

Needs and Uses: This collection will be submitted as an extension of a currently collection after this 60-day comment period to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance. The purpose of requiring a non-federal public safety entity to obtain written consent from its SWIC or state appointed official before communicating with federal government agencies on the Federal Interoperability Channels is to ensure that the non-federal public safety entity operates in accordance with the rules and procedures governing use of the federal interoperability channels and does not cause inadvertent interference during emergencies. Commission staff will use the written concurrence from the SWIC or state appointed official to determine if an applicant's proposed operation on the Federal Interoperability Channels conforms to the terms of an agreement signed by the SWIC or state appointed official with a federal user with a valid assignment from the National Telecommunications and Information Administration (NTIA) which has jurisdiction over the channels.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024-03216 Filed 2-15-24; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064-0022; -0137; -0148]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance
Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the request to renew the existing information collections described below (OMB Control No. 3064-0022; -0137; -0148). The notices of the proposed renewal for these information collections were previously published in the **Federal Register** on December 14, 2023, allowing for a 60-day comment period.

DATES: Comments must be submitted on or before March 18, 2024.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website:* <https://www.fdic.gov/resources/regulations/federal-register-publications/>.
- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m.

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.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel,

202–898–3767, mcabeza@fdic.gov, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

1. *Title:* Uniform Application/Uniform Termination for Municipal Securities Principal or Representative.

OMB Number: 3064–0022.

Forms: 6200/54; 6200/55.

Affected Public: Individuals, Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN [OMB No. 3064–0022]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
Uniform Application for Municipal Securities Principal or Representative (Form MSD–4) (Mandatory).	Reporting (On Occasion).	1	1	1:00	1
Uniform Termination Notice for Securities Principal or Representative (Form MSD–5) (Mandatory).	Reporting (On Occasion).	1	1	1:00	1
Total Annual Burden (Hours)	2

Source: FDIC.

General Description of Collection: The 1975 Amendments to the Securities Exchange Act of 1934 established a comprehensive framework for the regulation of the activities of municipal securities dealers. Under Section 15B(a) of the Securities Exchange Act, municipal securities dealers which are banks, or separately identifiable departments or divisions of banks engaging in municipal securities activities, are required to be registered with the Securities and Exchange Commission in accordance with such rules as the Municipal Securities Rulemaking Board (MSRB), a rulemaking authority established by the 1975 Amendments, may prescribe as necessary or appropriate in the public interest or for the protection of investors. One of the areas in which the Act directed the MSRB to promulgate rules is the qualifications of persons associated with municipal securities dealers as municipal securities

principals and municipal securities representatives. The MSRB Rules require persons who are or seek to be associated with municipal securities dealers as municipal securities principals or municipal securities representatives to provide certain background information and conversely, require the municipal securities dealers to obtain the information from such persons. Generally, the information required to be furnished relates to employment history and professional background including any disciplinary sanctions and any claimed bases for exemption from MSRB examination requirements. The FDIC and the other two Federal bank regulatory agencies, the Comptroller of the Currency, and the Federal Reserve Board, have prescribed Forms MSD–4 to satisfy these requirements and have prescribed Form MSD–5 for notification by a bank municipal securities dealer that a municipal securities principal’s or a

municipal securities representative’s association with the dealer has terminated and the reason for such termination. State nonmember banks and state savings associations that are municipal security dealers submit these forms, as applicable, to the FDIC as their appropriate regulatory agency for each person associated with the dealer as a municipal securities principal or municipal securities representative. There is no change in the methodology or substance of this information collection. This reduction in estimated annual burden (from 4 hours in 2021 to 2 hours currently) is due to the decrease in the estimated number of respondents.

2. *Title:* Interagency Guidance on Asset Securitization Activities.

OMB Number: 3064–0137.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0137]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Documentation of Fair Value, "Valuation and Modeling Processes," pp. 6–7 (Voluntary).	Recordkeeping (On Occasion).	19	1	04:00	76
2. Asset Securitization Policies—Implementation, "Independent Risk Management Function," pg. 4 (Voluntary).	Recordkeeping (On Occasion).	5	1	32:00	160
3. Asset Securitization Policies—Ongoing, "Independent Risk Management Function," pg. 4 (Voluntary).	Recordkeeping (On Occasion).	2	1	03:00	6
4. MIS Improvements—Implementation, "Independent Risk Management Function," pp. 4–6 (Voluntary).	Recordkeeping (On Occasion).	5	1	21:00	105
5. MIS Improvements—Ongoing, "Independent Risk Management Function," pp. 4–6, and "Audit Function or Internal Review," pg. 8 (Voluntary).	Recordkeeping (On Occasion).	2	1	05:00	10
Total Annual Burden (Hours)	357

Source: FDIC.

General Description of Collection: The Interagency Guidance on Asset Securitization Activities informs bankers and examiners of safe and sound practices regarding asset Securitization. The information collections contained in the Interagency Guidance are needed by institutions to manage their asset Securitization activities in a safe and sound manner. Bank management uses this information

as the basis for the safe and sound operation of their asset securitization activities and to ensure that they minimize operational risk in these activities. There is no change in the method or substance of the information collection. The 94-hour increase in estimated annual burden (from 263 hours in 2021 to 357 hours currently) is the result of economic fluctuation. In particular, the number of respondents

has increased while the reporting frequency and the estimated time per response remain the same.

3. *Title:* Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions, OMB Number: 3064–0148, Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0148]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
Complex Structured Finance Transactions (Voluntary).	Reporting (On occasion).	1	1	25:00	25
Total Annual Burden (Hours)	25

Source: FDIC.

General Description of Collection: The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify, evaluate, assess, document, and control the full range of credit, market, operational, legal and reputational risks. A financial institution that engages in complex structured finance transactions should maintain a set of formal, written, firm-wide policies and procedures that are designed to allow the institution to identify and assess these risks. There is

no change in the methodology or substance of this information collection. The estimated annual burden is unchanged.

Request for Comment: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on February 13, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–03283 Filed 2–15–24; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than March 18, 2024.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri, 64198-0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *Panhandle Bancshares, Inc., Guymon, Oklahoma*; to merge with Spearman Bancshares, Inc., and indirectly acquire First National Bank, both of Spearman, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-03289 Filed 2-15-24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM**Proposed Agency Information Collection Activities; Comment Request**

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Recordkeeping Provisions Associated with Stress Testing Guidance (FR 4202; OMB No. 7100-0348).

DATES: Comments must be submitted on or before April 16, 2024.

ADDRESSES: You may submit comments, identified by FR 4202, by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- *Email:* regs.comments@federalreserve.gov. Include the OMB number or FR number in the subject line of the message.

- *Fax:* (202) 452-3819 or (202) 452-3102.

- *Mail:* Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M-4775, 2001 C St NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M-4365A, 2001 C St NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays, except for Federal holidays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452-3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and

Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghrabi@frb.gov, (202) 452-3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection title: Recordkeeping Provisions Associated with Stress Testing Guidance.

Collection identifier: FR 4202.

OMB control number: 7100–0348.

General description of collection: The Stress Testing Guidance was issued jointly by the Board, Federal Deposit Insurance Corporation, and Office of the Comptroller of the Currency on May 17, 2012. The interagency guidance outlines high-level principles for stress testing practices applicable to all Board-supervised banking organizations with more than \$10 billion in total consolidated assets.

Frequency: As needed.

Respondents: Board-supervised banking organizations with more than \$10 billion in total consolidated assets. These include state member banks, bank holding companies, and all other institutions for which the Board is the primary federal supervisor.

Total estimated number of respondents: 135.

Total estimated annual burden hours: 13,920.¹

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–03217 Filed 2–15–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three

years, with revision, the Recordkeeping and Disclosure Requirements Associated with Regulation O (FR O; OMB No. 7100–0382).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghribi@frb.gov, (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at <https://www.reginfo.gov/public/do/PRAMain>. These documents are also available on the Federal Reserve Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Recordkeeping and Disclosure Requirements Associated with Regulation O.

Collection identifier: FR O.

OMB control number: 7100–0382.

Date: March 18, 2024.

General description of collection: The Board's Regulation O—Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks (12 CFR part 215) governs any extension of credit made by a member bank to an executive officer, director, or principal shareholder of the member bank, of any company of which the member bank is a subsidiary, and of any other subsidiary of that company. Regulation O prohibits extensions of

credit to insiders unless they are made on substantially the same terms (including interest rates and collateral) as those prevailing at the time for comparable transactions by the bank with other persons who are not employed by the bank and do not involve more than the normal risk of repayment or present other unfavorable features. In addition, Regulation O limits extensions of credit by a member bank to individual insiders and to all insiders, requires a member bank's board of directors to approve certain large extensions of credit, and sets forth recordkeeping and disclosure requirements.

Frequency: Event-generated.

Respondents: Insured depository institutions and uninsured member banks.

Total estimated number of respondents: 6,099.

Total estimated change in burden: 12,512.

Total estimated annual burden hours: 21,932.¹

Current actions: On September 28, 2023, the Board published a notice in the **Federal Register** (88 FR 66843) requesting public comment for 60 days on the extension, with revision, of the FR O. The FR O PRA clearance currently only lists member banks as respondents. The Board proposed to revise the FR O PRA clearance to reflect that the information collections included in Regulation O, by operation of statute, apply in practice to all insured depository institutions, regardless of whether they are member banks. This revision would be solely an administrative law matter, and would not actually impose new requirements on any institutions. While the proposed revision would not substantively increase burden for any institution, the administrative change would result in a larger reported burden of 21,932 hours. The comment period for this notice expired on November 27, 2023. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–03214 Filed 2–15–24; 8:45 am]

BILLING CODE 6210–01–P

¹ More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 4202.

¹ More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR O.

FEDERAL RESERVE SYSTEM**Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB**

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Reporting, Recordkeeping, and Disclosure Requirements Associated with Rules Regarding Availability of Information (FR 4035 collection identifier; OMB No. 7100–0381).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghrabi@frb.gov, (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at <https://www.reginfo.gov/public/do/PRAMain>. These documents are also available on the Federal Reserve Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Reporting, Recordkeeping, and Disclosure Requirements Associated with Rules Regarding Availability of Information.

Collection identifier: FR 4035.

OMB control number: 7100–0381.

General description of collection: The information collection consists of reporting, recordkeeping, and disclosure requirements under subpart C (Nonpublic Information Made Available to Supervised Financial Institutions, Governmental Agencies, and Others in Certain Circumstances) of the Rules Regarding Availability of Information (12 CFR part 261). Subpart C contains reporting requirements that enable third parties to request the Board's authorization to access, use, or further disclose confidential supervisory information or other nonpublic information of the Board, and that ensure that the Board is notified when any subpoena or other legally enforceable demand requires production of confidential supervisory information or other nonpublic information of the Board in the form of documents or testimony. Subpart C also contains one recordkeeping requirement related to a provision that allows supervised financial institutions to disclose confidential supervisory information to service providers if the disclosure is deemed necessary to the service provider's provision of services, and two disclosure requirements that apply when individuals are served with a subpoena, order, or other judicial or administrative process requiring the production of confidential supervisory information or other nonpublic information of the Board in the form of documents or testimony.

Frequency: Event-generated.

Respondents: Supervised financial institutions; State, local, and foreign agencies; entities exercising governmental authority; and any person, entity, agency, or authority.

Total estimated number of respondents: 105.

Total estimated annual burden hours: 83.¹

Current actions: On September 28, 2023, the Board published a notice in the **Federal Register** (88 FR 66847) requesting public comment for 60 days on the extension, without revision, of the FR 4035. The comment period for this notice expired on November 27, 2023. The Board did not receive any comments.

¹ More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 4035.

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–03215 Filed 2–15–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 18, 2024.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 S LaSalle State, Chicago, Illinois 60690–1414. Comments can also be sent electronically to Comments.applications@chi.frb.org.

1. First Financial Corporation, Terre Haute, Indiana; to acquire SimplyBank., Dayton, Tennessee, through a merger with a newly formed subsidiary, FFB Interim Bank N.A., Dayton, Tennessee.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions) 2200 N Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to Comments.applications@dal.frb.org.

1. *FSBH, Inc., Dallas, Texas*; to become a bank holding company by merging with Farmers Bancshares, Inc., and thereby indirectly acquiring Farmers State Bank, both of Center, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-03213 Filed 2-15-24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Margin Credit Reports (FR G-1, FR G-2, FR G-3, FR G-4, FR T-4, and FR U-1; OMB No. 7100-0011).

DATES: Comments must be submitted on or before April 16, 2024.

ADDRESSES: You may submit comments, identified by FR G-1, FR G-2, FR G-3, FR G-4, FR T-4, or FR U-1, by any of the following methods:

- **Agency website:** <https://www.federalreserve.gov/>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- **Email:** regs.comments@federalreserve.gov. Include the OMB number or FR number in the subject line of the message.

- **FAX:** (202) 452-3819 or (202) 452-3102.

- **Mail:** Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M-4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M-4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. on weekdays, except for Federal holidays.

For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452-3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghrabi@frb.gov, (202) 452-3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collection of information is necessary for the proper

performance of the Board's functions, including whether the information has practical utility;

- b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

- c. Ways to enhance the quality, utility, and clarity of the information to be collected;

- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

- e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Collection title: Margin Credit Reports.

Collection identifier: FR G-1, FR G-2, FR G-3, FR G-4, FR T-4, and FR U-1.

OMB control number: 7100-0011.

General description of collection: The Margin Credit Reports is comprised of the following six reports: Registration Statement for Persons Who Extend Credit Secured by Margin Stock (Other Than Banks, Brokers, or Dealers) (FR G-1), Deregistration Statement for Persons Registered Pursuant to Regulation U (FR G-2), Statement of Purpose for an Extension of Credit Secured by Margin Stock by a Person Subject to Registration Under Regulation U (FR G-3), Annual Report (FR G-4), Statement of Purpose for an Extension of Credit by a Creditor (FR T-4), and Statement of Purpose for an Extension of Credit Secured by Margin Stock (FR U-1). These reports relate to extensions of credit secured by margin stock. The Board collects the information gathered by the Margin Credit Reports so that it may meet certain obligations under the Securities Exchange Act of 1934.

Certain lenders that are not brokers, dealers, or banks making loans secured by margin stock must register and deregister with the Federal Reserve using the FR G-1 and FR G-2, respectively, and must file an annual report (FR G-4) while registered. The FR G-1, FR G-2, and FR G-4 reporting requirements collect data used to identify lenders subject to the Board's Regulation U to verify their compliance

with the regulation and to monitor margin credit.

The FR T-4, FR U-1, and FR G-3 are forms that implement recordkeeping requirements for brokers and dealers, banks, and other lenders, respectively. The FR T-4 documents the purpose of credit being extended when that credit is not to purchase, carry, or trade in securities and the credit is in excess of that otherwise permitted under Regulation T. The FR G-3 and FR U-1 document the purpose of loans secured by margin stock.

Proposed revisions: The Board proposes to revise the FR G-1 and FR G-4 by updating the confidentiality treatment as contained in the reporting instructions to state that individual respondents may request that information submitted to the Board through the FR G-1 and FR G-4 be kept confidential and the Board will evaluate whether such treatment is appropriate on a case-by-case basis. The reports currently state that the Board considers the information submitted to be confidential. The Board believes these changes more accurately reflect its obligations under the Privacy Act of 1974, 5 U.S.C. 552a. There are no changes being proposed to the FR G-2, FR G-3, FR T-4, or FR U-1.

Frequency: Event-generated.

Respondents: The FR G-1, FR G-2, FR G-3, and FR G-4 panels comprise lenders, other than banks, brokers, or dealers, that extend margin credit, including federal and state credit unions; insurance companies; commercial and consumer credit organizations; production credit associations; small businesses; insurance premium funding plans; plan-lenders (a company or its affiliate that extends credit to employees to purchase company stock under an eligible employee stock option or stock purchase plan); and lenders to Employee Stock Ownership Plans (ESOPs), thrift plans, and broker-dealer affiliates. The FR T-4 panel comprises brokers and dealers and the FR U-1 panel comprises banks.

Total estimated number of respondents: FR G-1, 25; FR G-2, 12; FR G-3, 10; FR G-4, 129; FR T-4, 14; FR U-1, 14.

Estimated average hours per response: FR G-1, 1.65; FR G-2, 0.53; FR G-3, 0.25; FR G-4, 2.07; FR T-4, 0.25; FR U-1, 0.25.

Total estimated annual burden hours: 697.¹

¹ More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/>

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-03221 Filed 2-15-24; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (FR 4100; OMB No. 7100-0309).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrahi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghrabi@frb.gov, (202) 452-3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at <https://www.reginfo.gov/public/do/PRAMain>. These documents are also available on the Federal Reserve Board's public website at <https://www.federal>

[apps/reportingforms/home/review](https://www.federalreserve.gov/apps/reportingforms/home/review). On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR GTU.

[reserve.gov/apps/reportingforms/home/review](https://www.federalreserve.gov/apps/reportingforms/home/review) or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice.

Collection identifier: FR 4100.

OMB control number: 7100-0309.

General description of collection: The FR 4100 is the Board's information collection associated with the Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (ID-Theft Guidance or Guidance). The ID-Theft Guidance was published in the **Federal Register** in March 2005.¹

The ID-Theft Guidance was issued in response to developing trends in the theft and accompanying misuse of customer information. The Guidance includes certain voluntary reporting, recordkeeping, and disclosure provisions.

Frequency: Event-generated.

Respondents: State member banks, bank holding companies (BHCs), affiliates and certain non-banking subsidiaries of BHCs, uninsured state agencies and branches of foreign banks, commercial lending companies owned or controlled by foreign banks, savings and loan holding companies, and Edge and agreement corporations.

Total estimated number of respondents: 391.

Total estimated annual burden hours: 12,120.²

Current actions: On September 28, 2023, the Board published a notice in the **Federal Register** (88 FR 66845) requesting public comment for 60 days on the extension, without revision, of the FR 4100. The comment period for this notice expired on November 27, 2023. The Board did not receive any comments.

¹ See 70 FR 15736 (March 29, 2005).

² More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 4100.

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-03220 Filed 2-15-24; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Recordkeeping Requirements Associated with Regulation F (FR F; OMB No. 7100-0331).

DATES: Comments must be submitted on or before April 16, 2024.

ADDRESSES: You may submit comments, identified by FR F, by any of the following methods:

- **Agency Website:** <https://www.federalreserve.gov/>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- **Email:** regs.comments@federalreserve.gov. Include the OMB number or FR number in the subject line of the message.

- **FAX:** (202) 452-3819 or (202) 452-3102.

- **Mail:** Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M-4775, 2001 C St. NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M-4365A, 2001 C St. NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays, except for Federal holidays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452-3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security

screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghribi@frb.gov, (202) 452-3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/> review or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

- b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

- c. Ways to enhance the quality, utility, and clarity of the information to be collected;

- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

- e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, Following Information Collection

Collection title: Recordkeeping Requirements Associated with Regulation F.

Collection identifier: FR F.

OMB control number: 7100-0331.

General description of collection: The Board's Regulation F—Limitations on Interbank Liabilities (12 CFR part 206) establishes limits on depository institutions' credit exposure to individual correspondents in order to mitigate the risk that the failure of a correspondent would pose to an insured depository institution.¹ Section 206.3 of Regulation F requires insured depository institutions to establish and maintain policies and procedures designed to prevent excessive exposure to correspondents.

Frequency: This information collection contains recordkeeping requirements. The creation of written policies and procedures concerning interbank liabilities is a mandatory one-time requirement. Subsequent changes to these policies and procedures would be on occasion, and they must be reviewed and approved by the depository institution's board of directors at least annually. The policies and procedures must be maintained, as amended.

Respondents: All depository institutions insured by the Federal Deposit Insurance Corporation (FDIC).²

Total estimated number of respondents: 4,655.

Total estimated annual burden hours: 4,753.³

¹ Correspondent means a U.S. depository institution or a foreign bank to which a bank has exposure but does not include a commonly controlled correspondent. 12 CFR 206.2(c).

² The Board takes burden under the Paperwork Reduction Act with respect to all such entities.

³ More detailed information regarding this collection, including more detailed burden

Board of Governors of the Federal Reserve System, February 12, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-03218 Filed 2-15-24; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-24-1408]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) received approval from the Office of Management and Budget (OMB) to conduct Rapid Surveys System (RSS)[OMB Control No. 0920-1408], which includes fielding four surveys per year. The Round 1 survey was approved on 06/30/2023. A second and third round of the RSS were additionally approved. In accordance with the Terms of Clearance, NCHS will publish a 30-day **Federal Register** Notice announcing each new survey so that public comments can be received about the specific content of each survey. This notice includes specific details about the questions that would be asked in the fourth round of the RSS and serves to allow 30 days for public and affected agency comments, consistent with OMB's terms of clearance.

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

Rapid Surveys System (RSS) Round 4 (OMB Control No. 0920-1408)—National Center for Health Statistics (NCHS) Centers for Disease Control and Prevention (CDC),

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C.), as amended, authorizes that the Secretary of Health and Human Services (HHS), acting through NCHS, collect data about the health of the population of the United States. The RSS (OMB control No. 0920-1408) collects data on emerging public health topics, attitudes, and behaviors using cross-sectional samples from two commercially available, national probability-based online panels. The RSS then combines these data to form estimates that approximate national representation in ways that many data collection approaches cannot. The RSS collects data in contexts in which decision makers' need for time-sensitive data of known quality about emerging and priority health concerns is a higher priority than their need for statistically unbiased estimates.

The RSS complements NCHS's current household survey systems. As quicker turnaround surveys that require less accuracy and precision than CDC's more rigorous population representative surveys, the RSS incorporates multiple mechanisms to carefully evaluate the resulting survey data for their

appropriateness for use in public health surveillance and research (e.g., hypothesis generating) and facilitate continuous quality improvement by supplementing these panels with intensive efforts to understand how well the estimates reflect populations at most risk. The RSS data dissemination strategy communicates the strengths and limitations of data collected through online probability panels as compared to more robust data collection methods.

The RSS has three major goals: (1) to provide CDC and other partners with time-sensitive data of known quality about emerging and priority health concerns; (2) to use these data collections to continue NCHS's evaluation of the quality of public health estimates generated from commercial online panels; and (3) to improve methods to communicate the appropriateness of public health estimates generated from commercial online panels.

The RSS is designed to have four rounds of data collection each year with data being collected by two contractors with probability panels. A cross-sectional nationally representative sample will be drawn from the online probability panel maintained by each of the contractors. As part of the base (minimum sample size), each round of data collection will collect 2,000 responses per quarter. The RSS can be expanded by increasing the number of completed responses per round or the number of rounds per year as needed up to a maximum of 28,000 responses per year per contractor or 56,000 total responses per year. Additionally, each data collection may include up to 2,000 additional responses per quarter (8,000 for the year) to improve representativeness. This increases the maximum burden by up to 16,000 responses per year. The RSS may also target individual surveys to collect data only from specific subgroups within existing survey panels and may supplement data collection for such groups with additional respondents from other probability or nonprobability samples. An additional 12,000 responses per year may be used for these developmental activities.

Each round's questionnaire will consist of four main components: (1) basic demographic information on respondents to be used as covariates in analyses; (2) new, emerging, or supplemental content proposed by NCHS, other CDC Centers, Institute, and Offices, and other HHS agencies; (3) questions used for calibrating the survey weights; and (4) additional content selected by NCHS to evaluate against relevant benchmarks. NCHS will use

estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR F.

questions from Components 1 and 2 to provide relevant, timely data on new, emerging, and priority health topics to be used for decision making. NCHS will use questions from Components 3 and 4 to weight and evaluate the quality of the estimates coming from questions in Components 1 and 2. Components 1 and 2 will contain different topics in each round of the survey. NCHS submits a 30-day **Federal Register** Notice with information on the contents of each round of data collection.

NCHS calibrates survey weights from the RSS to gold standard surveys. Questions used for calibration in this round of RSS will include marital status, employment, social and work limitations, use of the internet in general and for medical reasons, telephone use, civic engagement, and language used at home and in other settings. All of these questions have

been on the National Health Interview Survey (NHIS) in prior years allowing calibration to these data.

Finally, all RSS rounds will include several questions that were previously on NHIS or other NCHS surveys, or other suitable Federal surveys for benchmarking to evaluate data quality. Panelists in the RSS will be asked about health status; chronic conditions; pregnancy; disability and age of disability onset; health insurance through an employer; healthcare access and utilization; mental health; mental health care utilization; and health behaviors.

Rapid Surveys System (RSS) will include content on psychological aggression by intimate partners, sexual violence, technology-facilitated sexual violence, emerging coercive control by intimate partners, and traumatic brain

injury because of intimate partner violence.

In Round 4, the RSS will be used as a methodological study to test the ability to obtain data on intimate partner violence-related topics via web panel survey. In addition, RSS Round 4 offers the opportunity for developmental work to develop questions using a split sample to compare current NISVS questions and modified questions to evaluate different wording and question formats and to develop new questionnaire content related to understudied domains of intimate partner violence. The estimated total annual burden hours for the three-year approval period remains at 28,079 burden hours. The NCHS RSS Round 4 (2024) data collection is based on 13,100 complete surveys (4,367 hours). There are no costs to respondents 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)
Adults 18+	Survey: NCHS RSS Round 4 (2024)	13,100	1	20/60

Jeffrey M. Zirger,
*Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.*
[FR Doc. 2024–03242 Filed 2–15–24; 8:45 am]
BILLING CODE 4163–18–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Disease Control and
Prevention**

[30Day–24–0740]

**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 “Medical Monitoring Project (MMP)” 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 April 24, 2023 to obtain comments from the public and affected agencies. CDC received one 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

Medical Monitoring Project (MMP)—(OMB Control No. 0920–0740 Exp. 05/31/2024)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of HIV Prevention (DHP) requests a Revision of the currently approved Information Collection Request titled Medical Monitoring Project (MMP) (OMB Control No. 0920–0740, Expiration 5/31/2024). This data collection addresses the need for national estimates of access

to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

For the proposed project, the same data collection methods will be used as for the currently approved project. Data would be collected from a probability sample of HIV-diagnosed adults in the U.S. who consent to an interview and abstraction of their medical records. As for the currently approved project, de-identified information would also be extracted from HIV case surveillance records for a dataset (referred to as the minimum dataset), which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-diagnosed persons nationally. No other Federal agency collects such nationally representative population-based information from HIV-diagnosed

adults. The data are expected to have significant implications for policy, program development, and resource allocation at the State/local and national levels.

The changes proposed in this Revision request update the data collection system to meet prevailing information needs and enhance the value of MMP data, while remaining within the scope of the currently approved project purpose. The burden is the same as in the currently approved project. Changes were made that did not affect the burden are listed below:

- Revisions to the Interview Questionnaire were made to improve coherence, boost the efficiency of the data collection, and increase the relevance and value of the information. These changes did not affect the average burden per response.
- Revisions to the Medical Record Abstraction Data Elements were made to streamline the information collected and add important questions, such as

those related to mpox vaccination. Because the medical records are abstracted by MMP staff, these changes do not affect the burden of the project.

- The Interview and Medical Record data collection system were integrated to improve project efficiency and enhance data quality.

This proposed data collection would supplement the National HIV Surveillance System (NHSS, OMB Control No. 0920–0573, Exp. 02/28/2026) in 23 selected State and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS. Through their participation, respondents will help to improve programs to prevent HIV infection as well as services for those who already have HIV. Participation of respondents is voluntary. Total estimated annual burden requested is 5,707 hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
State and Local Health Departments	Interview Questionnaire	7,760	1	40/60
	Look up contact information	1,940	1	2/60
	Approach persons for enrollment	970	1	5/60
	Pull medical records	7,760	1	3/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–03240 Filed 2–15–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–1186]

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 “Information Collection for Tuberculosis Data from Referring Entities to CureTB” 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 December 15, 2023 to obtain comments from the public and affected agencies. CDC did not receive 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:

- 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 agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected;
- 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

- 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

Information Collection for Tuberculosis Data from Referring

Entities to CureTB (OMB Control No. 0920–1186, Exp. 02/29/2024)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CureTB program works to prevent the spread of tuberculosis (TB) among people who cross international borders. To reduce disease transmission and the emergence of drug-resistant TB, CureTB connects people with TB to healthcare services as they move between the United States and other countries. The program is a collaboration between CDC’s Division of Global Migration Health (DGMH) and the County of San Diego’s Tuberculosis Control Program. CureTB collaborates with health authorities throughout the United States and around the world to link people with TB to care at their destinations. Health departments, healthcare providers, and others seeking help in linking patients to ongoing TB care in other countries can refer patients to CureTB.

Information will be collected from the referring entities, which are State and local health departments and Federal

immigration and detention agencies. Whenever the referring entities provide clinical services to an individual with TB who has imminent plans to relocate, and an individual needs continuity of care in their new location, CDC CureTB is contacted to assist with coordinating that care. TB patients may also be a respondent if critical clinical or contact data is missing and requires follow-up by CureTB to complete a patient’s referral information set. The request for CDC CureTB services comes from the referring entities and they supply the information at the time the patient is likely to leave their jurisdiction. The referring entities update information only if relevant information to the patient’s care becomes available to them after their first communication with CDC CureTB. Therefore, information is already largely collected by CDC CureTB only at one point in time, with subsequent information only collected if departure is delayed or when initially pending information becomes available and this is beyond the control of CDC.

Post relocation of the TB patient, data is also collected from the receiving physicians to determine patient outcomes. CDC CureTB contacts the

physician an average of every two months during the standard six-month TB treatment process. The data provides valuable information on globally mobile populations and allows CDC to assist in continuity of TB care and monitor the effectiveness of the program.

The continuous expansion and use of the CureTB Program requires certain processes be evaluated. The Supplemental CureTB Program Partner Satisfaction Assessment Questionnaire will guide CureTB in making appropriate program improvements to best serve referring partners. The Questionnaires will not be used to collect demographic or clinical information, rather, they will ask the referring partners about their experience separately from the other forms already used for demographic and clinical information for each patient.

As part of this revision request, CureTB is updating the number of respondents and total burden hours. There are no changes to the data collection instruments. CDC requests OMB approval for an estimated 1,139 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
U.S. Health Departments	CureTB Transnational Notification	100	3	30/60
TB patients referred by U.S. health departments.	CureTB Transnational Notification	200	1	5/60
TB patients referred by ICE	CureTB Transnational Notification	600	1	45/60
TB treating physicians in new country	CureTB Telephone Script Clinician/foreign health authority Referral Follow-up.	900	3	10/60
U.S. Health Departments	CureTB Contact/Source Investigation (CI/SI) Notification.	20	5	30/60
U.S. Health Department (Local & State)	CureTB Partner Feedback (Satisfaction Assessment)—Questionnaire 1.	100	1	10/60
U.S. Health Department	CureTB Partner Feedback (Satisfaction Assessment)—Questionnaire 2.	50	1	6/60

Jeffrey M. Zirger,
Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.
[FR Doc. 2024–03241 Filed 2–15–24; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0138]

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 “Pulmonary Function Testing Course Approval Program” 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 October 30, 2023 to obtain comments from the public and affected agencies. CDC did not receive 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

Pulmonary Function Testing Course Approval Program. (OMB Control No. 0920-0138, Exp. 3/31/2024)—Extension—National Institute for

Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH has the responsibility under the Occupational Safety and Health Administration's Cotton Dust Standard, 29 CFR 1920.1043, for approving courses to train technicians to perform pulmonary function testing in the cotton industry. Successful completion of a NIOSH-approved course is mandatory under this Standard. In addition, regulations at 42 CFR 37.95(a) specify that persons administering spirometry tests for the national Coal Workers' Health Surveillance Program must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses. Also, 29 CFR 1910.1053(i)(2)(iv), 29 CFR 1910.1053(i)(3), 29 CFR 1926.1153(h)(2)(iv) and 29 CFR 1926.1153(h)(3) specify that pulmonary function tests for initial and periodic examinations in general industry and construction performed under the respirable crystalline silica standard should be administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course. To carry out its responsibility, NIOSH maintains a Pulmonary Function Testing Course Approval Program. The program consists of an application submitted by potential sponsors (universities, hospitals, and private consulting firms) who seek NIOSH approval to conduct courses, and if approved, notification to NIOSH of any course or faculty changes during the approval period, which is limited to five years. NIOSH is requesting a three-year approval.

The application form and added materials, including an agenda, curriculum vitae, and course materials are reviewed by NIOSH to determine if

the applicant has developed a program which adheres to the criteria required in the Standard. Following approval, any subsequent changes to the course are submitted by course sponsors via letter or email and reviewed by NIOSH staff to assure that the changes in faculty or course content continue to meet course requirements. Course sponsors also voluntarily submit an annual report to inform NIOSH of their class activity level and any faculty changes.

Sponsors who elect to have their approval renewed for an additional five year period submit a renewal application and supporting documentation for review by NIOSH staff to ensure the course curriculum meets all current standard requirements. Approved courses that elect to offer NIOSH-Approved Spirometry Refresher Courses must submit a separate application and supporting documents for review by NIOSH staff. Institutions and organizations throughout the country voluntarily submit applications and materials to become course sponsors and carry out training. Submissions are required for NIOSH to evaluate a course and determine whether it meets the criteria in the Standard and whether technicians will be adequately trained as mandated under the Standard.

NIOSH will disseminate a one-time customer satisfaction survey to course directors and sponsor representatives to evaluate our service to courses, the effectiveness of the program changes implemented since 2005, and the usefulness of potential Program enhancements. The annualized figures slightly overestimate the actual burden, due to rounding of the number of respondents for even allocation over the three-year clearance period. Application form contains no changes. The estimated annual burden to respondents is 178 hours. There will be no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Potential Sponsors	Initial Application	3	1	10
	Annual Report	34	1	30/60
	Report for Course Changes	24	1	30/60
	Renewal Application	13	1	6
	Refresher Course Application	3	1	8
	One-Time Customer Satisfaction Survey	34	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2024-03239 Filed 2-15-24; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10884 and
CMS-855A]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 16, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT:
William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10884 Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC) Services
CMS-855A Medicare Enrollment Application for Institutional Providers
Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC) Services; *Use:* Section 402(a)(1)(J) of the

Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring in ambulatory surgical centers providing services to Medicare beneficiaries.

The information required for the prior authorization request includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Prior to rendering the services, ASC providers should submit this information to the Medicare Administrative Contractors (MACs). Trained clinical reviewers at the MACs will review the information required for this collection to determine if the requested services are medically necessary and meet Medicare requirements. If an ASC provider does not submit a prior authorization request before rendering the service and submitting a claim to Medicare for payment, the MAC will request the required information from the ASC provider to determine if the service meets applicable Medicare coverage, coding, and payment rules before the claim is paid. *Form Number:* CMS-10884 (OMB Control Number: 0938-NEW); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits; *Number of Respondents:* 4,038; *Number of Responses:* 95,579; *Total Annual Hours:* 59,904. (For policy questions regarding this collection contact Kelly Wojciechowski at kelly.wojciechowski@cms.hhs.gov or Justin Carlisle at Justin.Carlisle@cms.hhs.gov).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application for Institutional Providers; *Use:* Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made.

The primary function of the CMS–855A Medicare enrollment application is to gather information from a certified provider or certified supplier (hereafter occasionally and collectively referenced as “provider(s)”) that tells us who it is, whether it meets certain qualifications to be a health care provider, where it practices or renders services, the identity of its owners, and other information necessary to establish correct claims payments. *Form Number:* CMS–855A (OMB control number: 0938–0685); *Frequency:* On occasion; *Affected Public:* Business or other for-profits, not-for-profit institutions; *Number of Respondents:* 45,473; *Total Annual Responses:* 217,493; *Total Annual Hours:* 41,120. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–03294 Filed 2–15–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Healthy Marriage and Responsible Fatherhood Performance Measures and Additional Data Collection (Office of Management and Budget #0970–0566)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Family Assistance (OFA), is requesting an extension with changes to its approved collection and reporting of performance measures about program operations, services, and clients served through the Healthy Marriage (HM) and Responsible Fatherhood (RF) grant programs. In an effort to gain a great understanding of how HMRF programs influence program participants and staff at an individual level, ACF proposes to add one open field to the quarterly narrative reports to capture information

about the experiences of HMRF participants and/or staff. ACF is requesting to extend approval, with the implementation of this change, for 3 years.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect 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 search function. You can also obtain copies of the proposed collection of information by emailing OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF proposes to continue collecting a set of Office of Management and Budget (OMB)-approved performance measures from all HMRF award recipients.

The HMRF performance measures collect standardized information in the following areas:

- Applicant characteristics;
- Program operations;
- Service delivery; and
- Participant outcomes:
 - Entrance survey, with five versions: (1) HM Program Entrance Survey for Adult-Focused Programs; (2) HM Program Entrance Survey for Youth-Focused Programs; (3) RF Program Entrance Survey for Community-Based Fathers; (4) RF Program Entrance Survey for Community-Based Mothers; and (5) RF Program Entrance Survey for Reentering Fathers.
 - Exit survey, with five versions: (1) HM Program Exit Survey for Adult-Focused Programs; (2) HM Program Exit Survey for Youth-Focused Programs; (3) RF Program Exit Survey for Community-Based Fathers; (4) RF Program Exit Survey for Community-Based Mothers; and (5) RF Program Exit Survey for Reentering Fathers.

The measures were developed in 2014 after extensive review of the research

literature and recipients’ past measures. They were revised in 2020 based on a targeted analysis of existing measures, feedback from key audiences, and discussions with ACF staff and the 2015 cohort of recipients. OMB approved these revised measures in 2021 and has approved a handful of non-substantive changes since then.

ACF also proposes to continue the OMB-approved quarterly reporting on the following measures, with minor changes as described:

- Semi-annual Performance Progress Report (PPR), with two versions: (1) Performance Progress Report for HM Programs, and (2) Performance Progress Report for RF Programs; and
- Quarterly Performance Report (QPR), with two versions: (1) Quarterly Performance Progress Report for HM Programs, and (2) Quarterly Performance Progress Report for RF Programs. ACF proposes to add a new text box to the QPRs to gather qualitative narratives of the experiences of HMRF participants and/or staff. This information will help build ACF’s understanding of how HMRF programs influence program participants and staff at an individual level.

ACF provides recipients with a web-based performance measures data collection system called nFORM 2.0 (Information, Family Outcomes, Reporting, and Management) to improve the efficiency of data collection and reporting and the quality of data. This system allows for streamlined and standardized submission of recipient performance data through regular progress reports and supports recipient-led and federal research projects.

ACF also proposes to continue the OMB-approved requirement for recipients to document their continuous quality improvement (CQI) planning and implementation using a CQI plan template that is completed outside of the nFORM system.

Respondents: Respondents include HM and RF award recipient staff and program applicants and participants (participants are called “clients”).

Annual Burden Estimates: The estimated number of respondents for each instrument has been adjusted to reflect experiences in the field to date. There is no change to the average estimated time per response of any instrument.

Instrument	Respondent	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
1: Applicant Characteristics	Program applicants	150,000	1	0.25	37,500	12,500
	Program staff	330	455	0.10	15,015	5,005
2: Program Operations	Program staff	110	12	0.32	422	141
3: Service Delivery Data	Program staff	1,650	86	0.50	70,950	23,650
4: Entrance and Exit Surveys	Program clients (entrance)	141,498	1	0.42	59,429	19,810
	Program clients (exit)	94,734	1	0.42	39,788	13,263
	Program staff (entrance and exit on paper)	220	351	0.10	7,722	2,574
5: Semi-annual Performance Progress Report (PPR)	Program staff	110	6	3	1,980	660
6: Quarterly Performance Report (QPR)	Program staff	110	6	1	660	220
7: CQI Plan	Program staff	110	3	4	1,320	440

Estimated Total Annual Burden

Hours: 78,263.

Authority: Sec. 403. [42 U.S.C. 603].

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024-03282 Filed 2-15-24; 8:45 am]

BILLING CODE 4184-73-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Administration for Children and Families Generic for Engagement Efforts (New Umbrella Generic)

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) to establish a new umbrella generic clearance to request information while engaging individuals and groups who could provide valuable information to inform ACF programs and work, including but not limited to those who are served or have been served by ACF, those with expertise in ACF program areas, and individuals invested in the outcomes of ACF research and evaluation. These engagement activities often need to be conducted quickly, to allow for sufficient time to inform project direction and decision-making. Additionally, planning for engagement activities is most often on a quick timeline and the standard timeline to comply with a full request under the Paperwork Reduction Act (PRA) often inhibits the ability to collect

information to inform these activities.

Therefore, an umbrella generic is necessary to allow for quick turnaround requests for similar information collections related to these activities.

DATES: *Comments due within 30 days of publication.* OMB must decide about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect 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 search function. You can also obtain copies of the proposed collection of information by emailing OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Executive Order (E.O.), Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985) ¹ emphasizes consulting with communities that have been historically underserved by Federal policies and programs and those with lived experience ² in ACF programs. The E.O. on Further Advancing Racial Equity and Support for Underserved Communities

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

² Assistant Secretary for Planning and Evaluation. (2021, December). *Methods and Emerging Strategies to Engage People with Lived Experience*. (Contract Number HHSP2332015000711). U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/47f62cae96710d1fa13b0f590f2d1b03/lived-experience-brief.pdf>.

Through the Federal Government ³ followed in 2023 and built on E.O. 13985, calling upon agencies to increase engagement with underserved communities and to “collaborate with OMB, as appropriate, to identify and develop tools and methods” to meet this goal. This generic mechanism is a tool that could directly address these E.O.s. Particularly many requirements outlined in section 3 and section 5 of the 2023 E.O.

Additionally, the Presidential Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-Based Policy Making, ⁴ the HHS Strategic Plan fiscal year (FY) 2022–2026, ⁵ ACF’s Strategic Plan, ⁶ and the ACF Evaluation Policy ⁷ discuss community engagement and inclusion in research. Consistent with these guidance documents, and to ensure meaningful involvement with a variety of individuals with diverse experiences and perspectives, ACF often conducts active engagement activities to inform various efforts, including research and evaluation.

Hearing the perspective of those affected by, experienced in, interested in, or potentially interested in ACF programs and similar programs is vital to ensure ACF is responsive to the needs of those it serves and that resources are, and programming is appropriate, useful, and relevant for audiences. Information collections under this generic would gather information from individuals

³ <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/16/executive-order-on-further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

⁴ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policy-making/>.

⁵ <https://www.hhs.gov/about/strategic-plan/2022-2026/index.html>.

⁶ <https://www.acf.hhs.gov/about/acf-strategic-plan-2022>.

⁷ <https://www.acf.hhs.gov/opre/report/acf-evaluation-policy>.

with diverse experiences and perspectives to inform ACF policies and programs. The information collected would allow for ongoing, two-way collaborative and actionable communications between ACF and its State, local and/or Tribal partners, program participants, communities served or affected by ACF programs, and or others experienced with or interested in ACF programs or similar programs.

ACF envisions using information collected to inform a variety of efforts and activities such as the improvement, planning, and implementation of research studies, program changes, development and dissemination of resources and products developed under ACF studies, regulatory activities, guidance, outreach and/or training activities. The specific types of information gathering methods included under the umbrella of this clearance will vary, but will use well-established methodologies, including but not limited to:

- Semi-structured discussions or conference calls
- Focus groups
- Telephone or in-person interviews
- Questionnaires/Surveys
- Roundtable and/or Breakout Sessions
- Open-ended requests
- Contextualizing Existing Data

Data collection will take place through a variety of activities—both in-person and virtual—dependent on the specific project. ACF will submit individual requests under this clearance. ACF requests OMB provide a response on individual generic information collections within 10 business days.

Respondents: Respondents could include current or prospective service providers, training and technical assistance providers, grant recipients, contractors, current and potential participants in ACF programs or other comparable groups and other individuals with lived experience with ACF or similar programs, experts in

fields pertaining to ACF programs, other key groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, State or local government officials, those in broader fields of study related to human services, or others involved in or prospectively involved in ACF programs.

Burden Estimates: The burden table below is illustrative. Estimates for the number of respondents and time per response have been made based on discussion with ACF program offices, but as this is a new umbrella generic, it may be possible that we will need to adjust estimates throughout the three-year approval period. If needed, ACF will submit a change request for these updates. While we will not exceed the total burden cap for this generic without requesting a change for updates, we may use more or less burden within each instrument type.

Example types of information collections	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Semi-Structured Discussions and Focus Groups	10,000	1	2	20,000
Interviews	4,500	1	1	4,500
Questionnaires/Surveys	8,000	1.5	.5	6,000
Templates and Open-ended requests	1,000	1	10	10,000
Estimated Totals	23,500	40,500

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024-03228 Filed 2-15-24; 8:45 am]

BILLING CODE 4184-88-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-5259]

Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that published in the **Federal Register** of December 22, 2023. In that notice, FDA requested comments on the draft guidance for industry entitled, “Master Protocols for

Drug and Biological Product Development.” The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance published December 22, 2023 (88 FR 88623). Submit either electronic or written comments by March 21, 2024, to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–5259 for “Master Protocols for Drug and Biological Product Development.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft 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 the 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Scott N. Goldie, Center for Drug Evaluation and Research, Office of Biostatistics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or James Myers Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 22, 2023, FDA published a notice of availability for a draft guidance entitled, “Master Protocols for Drug and Biological Product Development.” This action opened a docket with a 60-day comment period. The Agency received requests for an extension of the comment period for the draft guidance. After considering the requests, and in light of the fact that the original comment period is scheduled to close on February 20, 2024, FDA has decided to extend the comment period for 30 days, until March 21, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments to ensure that FDA can consider the comments before it begins work on the final version of the guidance.

Dated: February 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03296 Filed 2–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by April 16, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993-0002, 301-796-2398, PSG-Questions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on November 17, 2023 (88 FR 80315). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA’s website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Abacavir sulfate; Dolutegravir sodium; Lamivudine.
Adagrasib.
Amoxicillin; Clarithromycin; Vonoprazan fumarate.
Amoxicillin; Vonoprazan fumarate.
Baclofen.
Budesonide; Formoterol fumarate; Glycopyrrolate.
Caffeine; Ergotamine tartrate.
Durlobactam sodium; Durlobactam sodium; Sulbactam sodium.
Elagolix sodium, estradiol, norethindrone acetate; Elagolix sodium.
Ferric derisomaltose.
Finasteride; Tadalafil.
Flotufolastat F-18 gallium.
Formoterol fumarate; Glycopyrrolate.
Lenacapavir sodium (multiple reference listed drugs).
Mannitol (multiple reference listed drugs).

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Naloxone hydrochloride. Niraparib tosylate. Oltasidenib. Rivaroxaban. Sertraline hydrochloride. Sodium phenylbutyrate. Sodium phenylbutyrate; Taurursodiol. Terlipressin acetate. Testosterone undecanoate. Xenon Xe-129 hyperpolarized. Zanamivir.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

for industry for drug products containing the following active ingredients:

FDA is announcing the availability of revised draft product-specific guidances

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s).
Acidinium bromide. Acidinium bromide; Formoterol fumarate. Albuterol sulfate. Aprepitant. Betamethasone dipropionate; Clotrimazole (multiple reference listed drugs). Budesonide. Dapsone (multiple reference listed drugs). Dexamethasone; Neomycin sulfate; Polymyxin B sulfate. Dexamethasone; Tobramycin (multiple reference listed drugs). Diazepam. Doxepin hydrochloride. Ferric carboxymaltose. Fluorometholone. Fluticasone furoate; Umeclidinium bromide; Vilanterol trifenate. Fluticasone propionate (multiple reference listed drugs). Fluticasone propionate; Salmeterol xinafoate (multiple reference listed drugs). Hydrocortisone; Neomycin sulfate; Polymyxin b sulfate. Loteprednol etabonate (multiple reference listed drugs). Loteprednol etabonate; Tobramycin. Mometasone furoate. Nilotinib hydrochloride. Salmeterol xinafoate. Umeclidinium bromide. Umeclidinium bromide; Vilanterol trifenate. Vandetanib.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public.

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <http://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: February 9, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–03300 Filed 2–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2023-N-0008]

Request for Nominations for Voting Members for the Genetic Metabolic Diseases Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the request for nominations for voting members excluding consumer and industry representatives, to serve on the Genetic Metabolic Diseases Advisory Committee (the Committee) in the Center for Drug Evaluation and Research. This request for nominations was announced in the **Federal Register** of December 13, 2023. The amendment is being made to reflect a change in the **DATES** portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Moon Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-2894, email: GEMDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 13, 2023 (88 FR 86337), FDA announced a request for nominations for voting members excluding consumer and industry representatives, to serve on the Genetic Metabolic Diseases Advisory Committee. On page 86337, in the second column, the **DATES** portion of the document is changed to read as follows:

Nominations received on or before March 12, 2024, will be given first consideration for membership on the Committee. Nominations received after March 12, 2024, will be considered for nomination to the Committee as later vacancies occur.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 12, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.

[FR Doc. 2024-03302 Filed 2-15-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Advisory Committee on Training in Primary Care Medicine and Dentistry Meeting Cancellation**

AGENCY: Health Resources and Services Administration; Department of Health and Human Services.

ACTION: Notice of meeting cancellation.

SUMMARY: This is to notify the public that the March 25-26, 2024, meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry is cancelled.

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Officer, Advisory Committee on Training in Primary Care Medicine and Dentistry, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857, telephone: (301) 443-5260 or email: srogers@hrsa.gov.

SUPPLEMENTARY INFORMATION: This meeting was announced in the **Federal Register** on Friday, December 15, 2023 (88 FR 86909). Future meetings will be held on August 2, 2024, and another date this calendar year that will be announced at least 30 days before the meeting date through the **Federal Register**.

Maria G. Button,
Director, Executive Secretariat.

[FR Doc. 2024-03261 Filed 2-15-24; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Library of Medicine; Notice of Meeting Amended Notice of Meeting**

Notice is hereby given of a change in the virtual meeting of the Biomedical Library, Informatics and Data Science Review Committee, May 17-18, 2024, which was published in the **Federal Register** on December 21, 2023, 88 FR 88407.

The meeting will be amended to change the meeting dates from March 7-8, 2024, to March 7, 2024. The meeting will be closed to the public.

Dated: February 12, 2024.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-03212 Filed 2-15-24; 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; Notice of Closed Meeting**

Pursuant to section 1009 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Integration of Novel Measures for Improved Classification of Type 2 Diabetes Consortium Review.

Date: March 19, 2024.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-2242, jerkinsa@nidDK.nih.gov.

(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: February 12, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-03211 Filed 2-15-24; 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; Notice of Closed Meeting**

Pursuant to section 1009 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK RC2 Review.
Date: March 21, 2024.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-8886, sanoviche@mail.nih.gov.

(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: February 12, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-03208 Filed 2-15-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or 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 grant applications and/or contract proposals, the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Quantification of Drugs of Abuse and Related Substances Compounds in Biological Specimens.

Date: March 1, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827-4471, ramadanir@mail.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research.

Date: March 12, 2024.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Contact Person: Sudhirkumar U. Yanpallewar, M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 443-4577, sudhirkumar.yanpallewar@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: February 13, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-03327 Filed 2-15-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP-2024-0001]

Commercial Customs Operations Advisory Committee

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee management; notice of open Federal advisory committee meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, March 6, 2024, in Charleston, SC. The meeting will be open for the public to attend in person or via webinar. The in-person capacity is limited to 75 persons for public attendees.

DATES: The COAC will meet on Wednesday, March 6, 2024, from 1 p.m. to 5 p.m. eastern standard time (EST). Please note that the meeting may close early if the committee has completed its business. Registration to attend in-person and comments must be submitted no later than March 1, 2024.

ADDRESSES: The meeting will be held at the Doubletree Hilton, 7401 Northwood Boulevard, Charleston, SC 29406 in the Lower/Upper Altitude Ballroom. For virtual participants, the webinar link and conference number will be posted by 5 p.m. EST on March 5, 2024, at <https://www.cbp.gov/trade/stakeholder-engagement/coac>. For information or to request special assistance for the meeting, contact Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344-1440, as soon as possible.

Comments may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Search for Docket Number USCBP-2024-0001. To submit a comment, click the "Comment" button located on the top-left hand side of the docket page.

- **Email:** tradeevents@cbp.dhs.gov. Include Docket Number USCBP-2024-0001 in the subject line of the message.

Comments must be submitted in writing no later than March 1, 2024, and must be identified by Docket No. USCBP-2024-0001. All submissions received must also include the words "Department of Homeland Security." All comments received will be posted without change to <https://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings> and www.regulations.gov. Therefore, please refrain from including any personal information you do not wish to be posted. You may wish to view the Privacy and Security Notice, which is available via a link on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229, (202) 344-1440; or Ms. Felicia M. Pullam, Designated Federal Officer, at (202) 344-1440 or via email at tradeevents@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the authority of the Federal Advisory Committee Act, title 5 U.S.C. ch. 10. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of the Department of Homeland Security, the Secretary of the Department of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Pre-Registration: Meeting participants may attend either in person or via webinar. All participants who plan to participate in person must register using the method indicated below:

For members of the public who plan to participate in person, please register online at <https://cbptradeevents.certain.com/profile/15733> by 5 p.m. EST on March 1, 2024. For members of the public who are pre-registered to attend the meeting in person and later need to cancel, please do so by 5 p.m. EST on March 1, 2024, utilizing the following link: <https://cbptradeevents.certain.com/profile/15733>.

For members of the public who plan to participate via webinar, the webinar link and conference number will be posted by 5 p.m. EST on March 5, 2024, at <https://www.cbp.gov/trade/stakeholder-engagement/coac>. Registration is not required to participate virtually.

The COAC is committed to ensuring that all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Mrs. Latoria Martin at (202) 344-1440 as soon as possible.

Please feel free to share this information with other interested members of your organization or association.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

There will be a public comment period after each subcommittee update during the meeting on March 1, 2024. Speakers are requested to limit their comments to two minutes or less to facilitate greater participation. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page: <http://www.cbp.gov/trade/stakeholder-engagement/coac>.

Agenda

The COAC will hear from the current subcommittees on the topics listed below:

1. The Intelligent Enforcement Subcommittee will provide updates on the work completed and topics discussed in its working groups. The Antidumping/Countervailing Duty (AD/CVD) Working Group will provide updates regarding its work and discussions on importer compliance with AD/CVD requirements. For this quarter, CBP continued to work on revisions to the Statement of Work (SOW) for the Forced Labor Working Group. During the next quarter, the Forced Labor Working Group will begin meeting and having discussions under the revised SOW. The SOW may include objectives to enhance focus on technology best practices, stakeholder training and guidance, transparency, and monitoring progress of the implementation of prior recommendations made by COAC. The Intellectual Property Rights (IPR) Process Modernization Working Group will report on the continuation of the development of enhancements in communications between CBP, rights holders, and the trade community regarding enforcement actions. The Bond Working Group was placed on hiatus effective December 13, 2023, and does not anticipate providing an update.

2. The Next Generation Facilitation Subcommittee will provide updates on all its existing working groups, to include a new working group, and the transfer of an existing working group to this subcommittee. The Automated Commercial Environment (ACE) 2.0 Working Group had the chance to review the remaining business case scenarios for the Concept of Operations Document. The Customs Interagency Industry Working Group (CII) continues to work on identifying data redundancies to improve efficiencies for the government and the trade. A new working group, the Modernized Entry Processes Working Group (MEPWG), launched following the start of the 17th Term. The Broker Modernization Working Group (BMWG) has been transferred from the Rapid Response Subcommittee to this subcommittee. Finally, the Passenger Air Operations (PAO) Working Group continues to discuss with the Trusted Worker Program (eBadge) CBP Security Seal automated processing, automation of forms, and global entry/trusted traveler programs, and will provide an update on those discussions.

3. The Rapid Response Subcommittee had one active working group this

quarter, the United States-Mexico-Canada Agreement (USMCA) Chapter 7 Working Group. The working group met twice during this quarter. The group will discuss their determination that the goals of the Statement of Work have been met and that the group will go on hiatus starting February 1, 2024. The Broker Modernization Working Group (BMWG) is still an active working group but has been transferred from the Rapid Response Subcommittee to the Next Generation Facilitation Subcommittee.

4. The Secure Trade Lanes Subcommittee will provide updates on all seven of its active working groups: the Export Modernization Working Group, the In-Bond Working Group, the Trade Partnership and Engagement Working Group, the Pipeline Working Group, the Cross-Border Recognition Working Group, the De Minimis Working Group, and the Centers Working Group. The Export Modernization Working Group has continued its work on the Electronic Export Manifest Pilot Program and is specifically focused on the effects of progressive filing by the shipper to continuously update export information on successive dates rather than on a specific date. The In-Bond Working Group has continued its focus on the implementation of prior recommendations made by COAC. The Trade Partnership and Engagement Working Group has continued its work on the elements of the Customs Trade Partnership Against Terrorism (CTPAT) security program and the validation process. The Pipeline Working Group has continued discussing the most appropriate “next step” commodities and potential users of Distributed Ledger Technology to engage once the pilot for tracking pipeline-borne goods deploys. The Cross-Border Recognition Working Group began to meet again to develop tasks specific to its Statement of Work. The De Minimis Working Group has continued its work on strengthening the supply chain and mitigating risks in the low-value package environment. The Centers Working Group, new to this subcommittee, has begun work towards the goals of its Statement of Work.

Meeting materials will be available on February 26, 2024, at: <http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings>.

Felicia M. Pullam,

Executive Director, Office of Trade Relations.

[FR Doc. 2024-03260 Filed 2-15-24; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID FEMA–2024–0002; Internal Agency Docket No. FEMA–B–2408]

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 May 16, 2024.

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–2408, to Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacibit@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.”)

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Hardin County, Illinois and Incorporated Areas Project: 12–05–8929S Preliminary Date: December 14, 2023	
City of Rosiclare	City Hall, 632 Main Street, Rosiclare, IL 62982.
Unincorporated Areas of Hardin County	Hardin County Courthouse, 102 East Market Street, Elizabethtown, IL 62931.

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****[Docket ID FEMA–2024–0002]****Changes in Flood Hazard Determinations**

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at <https://msc.fema.gov>.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacibit@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 flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations 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.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being

already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, 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.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at <https://msc.fema.gov>.

(Catalog of Federal Domestic Assistance No. 97.022, “Flood Insurance.”)

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Arizona:					
Maricopa (FEMA Docket No.: B–2365).	City of Glendale (22–09–1673P).	The Honorable Jerry Weiers, Mayor, City of Glendale, 5850 West Glendale Avenue, Suite 451, Glendale, AZ 85301.	City Hall, 5850 West Glendale Avenue, Glendale, AZ 85301.	Nov. 24, 2023	040045
Maricopa (FEMA Docket No.: B–2373).	City of Glendale (23–09–0431P).	The Honorable Jerry Weiers, Mayor, City of Glendale, 5850 West Glendale Avenue, Suite 451, Glendale, AZ 85301.	City Hall, 5850 West Glendale Avenue, Glendale, AZ 85338.	Dec. 8, 2023	040045
Maricopa (FEMA Docket No.: B–2373).	City of Goodyear (23–09–0431P).	The Honorable Joe Pizzillo, Mayor, City of Goodyear, 1900 North Civic Square, Goodyear, AZ 85395.	Engineering Department, 14455 West Van Buren Street, Suite D101, Goodyear, AZ 85338.	Dec. 8, 2023	040046
Maricopa (FEMA Docket No.: B–2373).	City of Surprise (22–09–1771P).	The Honorable Skip Hall, Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85374.	Public Works Department, Engineering Development Services, 16000 North Civic Center Plaza, Surprise, AZ 85374.	Dec. 22, 2023	040053
Maricopa (FEMA Docket No.: B–2365).	Unincorporated Areas of Maricopa County (22–09–1673P).	The Honorable Clint L. Hickman, Chair, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Glendale, AZ 85301.	Nov. 24, 2023	040037
Maricopa (FEMA Docket No.: B–2373).	Unincorporated Areas of Maricopa County (22–09–1771P).	The Honorable Clint L. Hickman, Chair, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	Dec. 22, 2023	040037
Maricopa (FEMA Docket No.: B–2373).	Unincorporated Areas of Maricopa County (23–09–0431P).	The Honorable Clint L. Hickman, Chair, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	Dec. 8, 2023	040037

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Yuma (FEMA Docket No.: B-2365).	Town of Wellton (22-09-1369P).	The Honorable Scott Blitz, Mayor, Town of Wellton, 28634 Oakland Avenue, Wellton, AZ 85356.	Town Hall, 28634 Oakland Avenue, Wellton, AZ 85356.	Dec. 6, 2023	040112
Arkansas:					
Benton (FEMA Docket No.: B-2365).	City of Lowell (22-06-2961P).	The Honorable Chris Moore, Mayor, City of Lowell, 216 North Lincoln Street, Lowell, AR 72745.	City Hall, 216 North Lincoln Street, Lowell, AR 72745.	Nov. 2, 2023	050342
Benton (FEMA Docket No.: B-2365).	City of Springdale (22-06-2961P).	The Honorable Doug Sprouse, Mayor, City of Springdale, 201 Spring Street, Springdale, AR 72764.	City Hall, 201 Spring Street Springdale, AR 72764.	Nov. 2, 2023	050219
California:					
Fresno (FEMA Docket No.: B-2373).	City of Clovis (22-09-0533P).	The Honorable Lynne Ashbeck, Mayor, City of Clovis, 1033 5th Street, Clovis, CA 93612.	City Clerk's Office, Civic Center, 1033 5th Street, Clovis, CA 93612.	Dec. 28, 2023	060044
Orange (FEMA Docket No.: B-2365).	City of San Juan Capistrano (23-09-0982X).	The Honorable Howard Hart, Mayor, City of San Juan Capistrano, 30448 Rancho Viejo Road, San Juan Capistrano, CA 92675.	City Hall, 32400 Paseo Adelanto, San Juan Capistrano, CA 92675.	Nov. 17, 2023	060231
Placer (FEMA Docket No.: B-2373).	Unincorporated Areas of Placer County (23-09-0551P).	The Honorable Jim Holmes, Chair, Board of Supervisors, Placer County, 175 Fulweiler Avenue, Auburn, CA 95603.	Placer County Public Works, 3091 County Center Drive, Suite 220, Auburn, CA 95603.	Dec. 22, 2023	060239
Riverside (FEMA Docket No.: B-2365).	City of Corona (22-09-1531P).	The Honorable Tony Daddario, Mayor, City of Corona, 400 South Vicentia Avenue, Corona, CA 92882.	City Hall, 400 South Vicentia Avenue, Corona, CA 92882.	Dec. 6, 2023	060250
Riverside (FEMA Docket No.: B-2365).	City of Corona (23-09-0461P).	The Honorable Tony Daddario, Mayor, City of Corona, 400 South Vicentia Avenue, Corona, CA 92882.	City Hall, 400 South Vicentia Avenue, Corona, CA 92882.	Nov. 9, 2023	060250
Riverside (FEMA Docket No.: B-2373).	City of Hemet (23-09-0353P).	The Honorable Joe Males, Mayor, City of Hemet, 445 East Florida Avenue, Hemet, CA 92543.	Engineering Department, 510 East Florida Avenue, Hemet, CA 92543.	Dec. 14, 2023	060253
Riverside (FEMA Docket No.: B-2365).	City of Riverside (22-09-1386P).	The Honorable Patricia Lock Dawson, Mayor, City of Riverside, 3900 Main Street, Riverside, CA 92522.	Public Works Department, 3900 Main Street, 4th Floor, Riverside, CA 92522.	Dec. 6, 2023	060260
Riverside (FEMA Docket No.: B-2365).	City of Riverside (23-09-0172P).	The Honorable Patricia Lock Dawson, Mayor, City of Riverside, 3900 Main Street, Riverside, CA 92522.	Public Works Department, 3900 Main Street, 4th Floor, Riverside, CA 92522.	Nov. 14, 2023	060260
Riverside (FEMA Docket No.: B-2373).	Unincorporated Areas of Riverside County (22-09-1127P).	The Honorable Kevin Jeffries, Chair, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501.	Riverside County, Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.	Jan. 11, 2024	060245
Riverside (FEMA Docket No.: B-2365).	Unincorporated Areas of Riverside County, (22-09-1531P).	The Honorable Kevin Jeffries, Chair, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501.	Riverside County, Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.	Dec. 6, 2023	060245
Riverside (FEMA Docket No.: B-2365).	Unincorporated Areas of Riverside County (23-09-0172P).	The Honorable Kevin Jeffries, Chair, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92522.	Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.	Nov. 14, 2023	060245
Riverside (FEMA Docket No.: B-2373).	Unincorporated Areas of Riverside County (23-09-0353P).	The Honorable Kevin Jeffries, Chair, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501.	Riverside County, Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.	Dec. 14, 2023	060245
San Diego (FEMA Docket No.: B-2373).	Unincorporated Areas of San Diego County (22-09-0129P).	The Honorable Nora Vargas, Chair, Board of Supervisors, San Diego County, 1600 Pacific Highway Room 335, San Diego, CA 92101.	San Diego County Flood Control District, Department of Public Works, 5510 Overland Avenue Suite 410, San Diego, CA 92123.	Dec. 27, 2023	060284
San Joaquin (FEMA Docket No.: B-2365).	Unincorporated Areas of San Joaquin County (23-09-0364P).	The Honorable Robert Rickman, Chair, Board of Supervisors, San Joaquin County, 44 North San Joaquin Street, Suite 627, Stockton, CA 95202.	San Joaquin County, Public Works Department, 1810 East Hazelton Avenue, Stockton, CA 95205.	Nov. 9, 2023	060299
Florida:					
Duval (FEMA Docket No.: B-2373).	City of Jacksonville (23-04-2806P).	The Honorable Lenny Curry, Mayor, City of Jacksonville, Mayor's Office, 117 West Duval Street Suite 400, Jacksonville FL 32202.	Edward Ball Building Development Services, 214 North Hogan Street, Room 2100, Jacksonville, FL 32202.	Dec. 14, 2023	120077
St. Johns (FEMA Docket No.: B-2373).	Unincorporated Areas of St. Johns County (23-04-0792P).	Henry Dean, Commissioner, District 5, St. Johns County, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County Permit Center, 4040 Lewis Speedway, St. Johns County, FL 32084.	Dec. 14, 2023	125147
St. Johns (FEMA Docket No.: B-2373).	Unincorporated Areas of St. Johns County (23-04-0824P).	Henry Dean, Commissioner, District 5, St. Johns County, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County Permit Center, 4040 Lewis Speedway, St. Augustine, FL 32084.	Dec. 19, 2023	125147
Walton (FEMA Docket No.: B-2365).	City of Freeport (22-04-4474P).	The Honorable Russ Barley, Mayor, City of Freeport, 112 Highway 20 West Freeport, FL 32439.	City Hall, 112 Highway 20 West, Freeport, FL 32439.	Nov. 9, 2023	120319
Walton (FEMA Docket No.: B-2365).	Unincorporated Areas of Walton County (22-04-4474P).	Danny Glidewell, District 2 Commissioner-Chair, Walton County, 76 North 6th Street, DeFuniak Springs, FL 32433.	Walton County Planning and Development Services Department, 31 Coastal Centre Boulevard, Santa Rosa Beach, FL 32459.	Nov. 9, 2023	120317

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Hawaii: Maui (FEMA Docket No.: B-2365).	Maui County (22-09-0588P).	The Honorable Richard T. Bissen, Jr., Mayor, County of Maui, 200 South High Street, Kalana O Maui Building 9th Floor, Wailuku, HI 96793.	County of Maui Planning Department, One Main Plaza, 2200 Main Street, Suite 315, Wailuku, HI 96793.	Nov. 29, 2023	150003
Illinois:					
DuPage (FEMA Docket No.: B-2373).	City of Naperville (22-05-2659P).	The Honorable Scott A. Wehrli, Mayor, City of Naperville, Municipal Center, 400 South Eagle Street, Naperville, IL 60540.	Municipal Center, 400 South Eagle Street, Naperville, IL 60540.	Jan. 8, 2024	170213
DuPage (FEMA Docket No.: B-2373).	Unincorporated Areas of DuPage County (22-05-2659P).	Deborah Conroy, Chair, DuPage County Board, 421 North County Farm Road, Wheaton, IL 60187.	DuPage County Administration Building, Stormwater Management, 421 North County Farm Road, Wheaton, IL 60187.	Jan. 8, 2024	170197
Will (FEMA Docket No.: B-2373).	City of Joliet (23-05-1511P).	The Honorable Terry D'Arcy, Mayor, City of Joliet, 150 West Jefferson Street, Joliet, IL 60432.	City Hall, 150 West Jefferson Street, Joliet, IL 60432.	Jan. 2, 2024	170702
Will (FEMA Docket No.: B-2373).	Village of Plainfield (23-05-0385P).	John Argoudelis, Village President, Village of Plainfield, 24401 West Lockport Street, Plainfield, IL 60544.	Village Hall, 24401 West Lockport Street, Plainfield, IL 60544.	Jan. 8, 2024	170771
Minnesota:					
Carver (FEMA Docket No.: B-2365).	City of Waconia (22-05-1488P).	The Honorable Nicole Warden, Mayor, City of Waconia, 201 South Vine Street, Waconia, MN 55387.	City Hall, 201 South Vine Street, Waconia, MN 55387.	Nov. 24, 2023	270055
Carver (FEMA Docket No.: B-2365).	Unincorporated Areas of Carver County (22-05-1488P).	John P. Fahey, Chair, Carver County Board of County Commissioners, 211 Park Place, Norwood Young America, MN 55368.	Carver County Public Health and Environment, 600 East 4th Street, Chaska, MN 55318.	Nov. 24, 2023	270049
Missouri:					
Jackson (FEMA Docket No.: B-2373).	City of Kansas City (23-07-0053P).	The Honorable Quinton Lucas, Mayor, City of Kansas City, 414 East 12th Street, 29th Floor, Kansas City, MO 64106.	Federal Office Building, 911 Walnut Street, Kansas City, MO 64106.	Dec. 13, 2023	290173
St. Charles (FEMA Docket No.: B-2373).	City of Cottleville (22-07-0821P).	The Honorable Bob Ronkoski, Mayor, City of Cottleville, 5490 5th Street, Cottleville, MO 63304.	City Hall, 5490 5th Street, Cottleville, MO 63304.	Sep. 22, 2023	290898
St. Charles (FEMA Docket No.: B-2373).	City of O'Fallon (22-07-0821P).	The Honorable Bill Hennessy, Mayor, City of O'Fallon, 100 North Main Street, O'Fallon, MO 63366.	City Hall, 100 North Main Street, O'Fallon, MO 63366.	Sep. 22, 2023	290316
St. Charles (FEMA Docket No.: B-2373).	Unincorporated Areas of St. Charles County (22-07-0821P).	Steve Ehlmann, County Executive, St. Charles County, 100 North 2nd Street Suite 318, St. Charles, MO 63301.	St. Charles County Administration Building, 201 North 2nd Street, Suite 420, St. Charles, MO 63301.	Sep. 22, 2023	290315
New York:					
Suffolk (FEMA Docket No.: B-2365).	Town of Southampton (23-02-0078P).	Jay Schneiderman, Town Supervisor, Town of Southampton, 116 Hampton Road, Southampton, NY 11968.	Town Hall, 116 Hampton Road, Southampton, NY 11968.	Dec. 21, 2023	365342
Suffolk (FEMA Docket No.: B-2365).	Village of Westhampton Beach (23-02-0078P).	The Honorable Gary Vegliante, Mayor, Village of Westhampton, 165 Mill Road, Westhampton Beach, NY 11978.	Village Hall, 165 Mill Road, Westhampton Beach, NY 11978.	Dec. 21, 2023	365345
Ohio:					
Butler (FEMA Docket No.: B-2365).	Unincorporated Areas of Butler County (22-05-1307P).	T.C. Rogers, President, Butler County Board of Commissioners, Government Services Center, 315 High Street, 6th Floor, Hamilton, OH 45011.	Butler County Administrator Center, Building and Zoning Department, 130 High Street, 1st Floor, Hamilton, OH 45011.	Nov. 27, 2023	390037
Franklin (FEMA Docket No.: B-2365).	Unincorporated Areas of Franklin County (22-05-1492P).	John O'Grady, Commissioner, Franklin County Board of Commissioners, 373 South High Street 26th Floor, Columbus, OH 43215.	Franklin County, Development Department, 280 East Broad Street, Columbus, OH 43215.	Dec. 5, 2023	390167
Franklin (FEMA Docket No.: B-2365).	Village of Canal Winchester (22-05-1492P).	The Honorable Michael Ebert, Mayor, Village of Canal Winchester, Municipal Building, 45 East Waterloo Street, Canal Winchester, OH 43110.	Planning and Zoning, 36 South High Street, Canal Winchester, OH 43110.	Dec. 5, 2023	390169
Oregon: Multnomah (FEMA Docket No.: B-2373).	City of Gresham (23-10-0228P).	The Honorable Travis Stovall, Mayor, City of Gresham, City Hall, 1333 Northwest Eastman Parkway, 3rd Floor, Gresham, OR 97030.	City Hall, 1333 Northwest Eastman Parkway, Gresham, OR 97030.	Dec. 28, 2023	410181
Texas:					
Dallas (FEMA Docket No.: B-2365).	City of Grand Prairie (22-06-0112P).	The Honorable Ron Jensen, Mayor, City of Grand Prairie, 300 West Main Street, Grand Prairie, TX 75053.	City Development Center, 206 West Church Street, Grand Prairie, TX 75050.	Nov. 22, 2023	485472
Dallas (FEMA Docket No.: B-2365).	City of Irving (22-06-0112P).	The Honorable Rick Stopfer, Mayor, City of Irving, City Hall, 825 West Irving Boulevard, Irving, TX 75060.	Capital Improvement Program Department, 825 West Irving Boulevard, Irving, TX 75060.	Nov. 22, 2023	480180
Tarrant (FEMA Docket No.: B-2365).	City of Arlington (22-06-2179P).	The Honorable Jim Ross, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	City Hall, 101 West Abram Street, Arlington, TX 76010.	Nov. 6, 2023	485454

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Tarrant (FEMA Docket No.: B-2365).	City of Fort Worth (23-06-1016X).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	Oct. 23, 2023	480596
Tarrant (FEMA Docket No.: B-2365).	City of Haltom City (21-06-2662P).	The Honorable An Truong, Mayor, City of Haltom City, City Hall, 5024 Broadway Avenue, Haltom City, TX 76117.	City Hall, 5024 Broadway Avenue, Haltom City, TX 76117.	Nov. 22, 2023	480599
Tarrant (FEMA Docket No.: B-2365).	City of North Richland Hills (21-06-2662P).	The Honorable Oscar Trevino, Jr., Mayor, City of North Richland Hills, City Hall, P.O. Box 820609, North Richland Hills, TX 76182.	City Hall, 4301 City Point Drive, North Richland Hills, TX 76180.	Nov. 22, 2023	480607
Virginia:					
Roanoke (FEMA Docket No.: B-2373).	City of Roanoke (23-03-0152P).	The Honorable Sherman P. Lea, Sr., Mayor, City of Roanoke, Noel C. Taylor Municipal Building, 215 Church Avenue, Roanoke, VA 24011.	Engineering Department, Noel C. Taylor Municipal Building, 215 Church Avenue, Roanoke, VA 24011.	Dec. 22, 2023	510130
Roanoke (FEMA Docket No.: B-2373).	City of Salem (23-03-0152P).	The Honorable Renee Turk, Mayor, City of Salem, 114 North Broad Street, Salem, VA 24153.	Office of the Building Official, 1238 West Main Street, Salem, VA 24153.	Dec. 22, 2023	510141
Roanoke (FEMA Docket No.: B-2373).	Town of Vinton (23-03-0152P).	The Honorable Bradley E. Grose, Mayor, Town of Vinton, 311 South Pollard Street, Vinton, VA 24179.	Planning and Zoning Department, 311 South Pollard Street, Vinton, VA 24179.	Dec. 22, 2023	510131
Roanoke (FEMA Docket No.: B-2373).	Unincorporated Areas of Roanoke County (23-03-0152P).	Martha B. Hooker, Chair, Roanoke County Board of Supervisors, P.O. Box 29800, Roanoke, VA 24018.	Roanoke County Community Development, 5204 Bernard Drive Southwest, Roanoke, VA 24018.	Dec. 22, 2023	510190
Washington:					
Kittitas (FEMA Docket No.: B-2365).	City of Cle Elum (21-10-1313P).	The Honorable Jay McGowan, Mayor, City of Cle Elum, 119 West 1st Street, Cle Elum, WA 98922.	City Hall, 119 West 1st Street, Cle Elum, WA 98922.	Dec. 8, 2023	530096
Kittitas (FEMA Docket No.: B-2365).	City of Roslyn (21-10-1313P).	The Honorable Brent Hals, Mayor, City of Roslyn, P.O. Box 451, Roslyn, WA 98941.	City Hall, 201 South 1st Street, Roslyn, WA 98941.	Dec. 8, 2023	530299
Kittitas (FEMA Docket No.: B-2365).	Unincorporated Areas of Kittitas County (21-10-1313P).	Cory Wright, Commissioner, Kittitas County Board of Commissioners, 205 West 5th Avenue Suite 108, Ellensburg, WA 98926.	Kittitas County, Department of Public Works, 411 North Ruby Street, Suite 1, Ellensburg, WA 98926.	Dec. 8, 2023	530095
Wisconsin:					
Outagamie (FEMA Docket No.: B-2373).	City of Kaukauna (22-05-2660P).	The Honorable Anthony Penterman, Mayor, City of Kaukauna, 144 West 2nd Street, Kaukauna, WI 54130.	City Hall, 201 West 2nd Street, Kaukauna, WI 54130.	Jan. 4, 2024	550305
Outagamie (FEMA Docket No.: B-2373).	Unincorporated Areas of Outagamie County (22-05-2660P).	Thomas Nelson, Executive, Outagamie County, County Building, 410 South Walnut Street, Appleton, WI 54911.	Outagamie County Building, 410 South Walnut Street, Appleton, WI 54911.	Jan. 4, 2024	550302

[FR Doc. 2024-03262 Filed 2-15-24; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2024-0002; Internal Agency Docket No. FEMA-B-2411]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of

Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and

must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is 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.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbabit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbabit@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 specific flood hazard determinations are not described for each community in

this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

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).

These 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. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is 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.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado: Jefferson	Unincorporated areas of Jefferson County (23-08-0153P).	Andy Kerr, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	https://msc.fema.gov/portal/advanceSearch .	Apr. 19, 2024	080087
Delaware: New Castle	Unincorporated areas of New Castle County (23-03-0281P).	Matthew Meyer, New Castle County Executive, 87 Reads Way, New Castle, DE 19720.	New Castle County Land Use Department, 87 Reads Way, New Castle, DE 19720.	https://msc.fema.gov/portal/advanceSearch .	Apr. 18, 2024	105085
New Castle	Unincorporated areas of New Castle County (23-03-0452P).	Matthew Meyer, New Castle County Executive, 87 Reads Way, New Castle, DE 19720.	New Castle County Land Use Department, 87 Reads Way, New Castle, DE 19720.	https://msc.fema.gov/portal/advanceSearch .	Mar. 14, 2024	105085
Florida: Bay	Unincorporated areas of Bay County (23-04-2123P).	Robert Majka, Bay County Manager, 840 West 11th Street, Panama City, FL 32401.	Bay County Planning and Zoning Department, 840 West 11th Street, Panama City, FL 32401.	https://msc.fema.gov/portal/advanceSearch .	Mar. 14, 2024	120004
Charlotte	Unincorporated areas of Charlotte County (23-04-1941P).	Bill Truex, Chair, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Building Department, 18400 Murdock Circle, Port Charlotte, FL 33948.	https://msc.fema.gov/portal/advanceSearch .	Mar. 14, 2024	120061
Charlotte	Unincorporated areas of Charlotte County (23-04-6087P).	Bill Truex, Chair, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Building Department, 18400 Murdock Circle, Port Charlotte, FL 33948.	https://msc.fema.gov/portal/advanceSearch .	Apr. 8, 2024	120061
Lee	City of Fort Myers (23-04-3576P).	Marty Lawing, City of Fort Myers Manager, 2200 2nd Street, Fort Myers, FL 33901.	Building Department, 1825 Hendry Street, Fort Myers, FL 33901.	https://msc.fema.gov/portal/advanceSearch .	Apr. 15, 2024	125106
Lee	Unincorporated areas of Lee County (23-04-3576P).	David Harner, Lee County Manager, P.O. Box 398, Fort Myers, FL 33902.	Lee County Building Department, 1500 Monroe Street, Fort Myers, FL 33901.	https://msc.fema.gov/portal/advanceSearch .	Apr. 15, 2024	125124

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Manatee	Unincorporated areas of Manatee County (23-04-0090P).	Charlie Bishop, Manatee County Administrator, 1112 Manatee Avenue West, Bradenton, FL 34205.	Manatee County Administration Building, 1112 Manatee Avenue West, Bradenton, FL 34205.	https://msc.fema.gov/portal/advanceSearch .	Apr. 26, 2024	120153
Marion	Unincorporated areas of Marion County (23-04-5915P).	Michelle Stone, Chair, Marion County Board of Commissioners, 601 Southeast 25th Avenue, Ocala, FL 34471.	Marion County Administration Building, 601 Southeast 25th Avenue, Ocala, FL 34471.	https://msc.fema.gov/portal/advanceSearch .	Apr. 26, 2024	120160
Osceola	City of St. Cloud (23-04-3875P).	Veronica Miller, City of St. Cloud Manager, 1300 9th Street, St. Cloud, FL 34769.	City Hall, 1300 9th Street, St. Cloud, FL 34769.	https://msc.fema.gov/portal/advanceSearch .	Apr. 26, 2024	120191
Maine: Lincoln	Town of Boothbay Harbor (23-01-0799P).	Julia Latter, Town Boothbay Harbor Manager, 11 Howard Street, Boothbay Harbor, ME 04538.	Code Enforcement Department, 11 Howard Street, Boothbay Harbor, ME 04538.	https://msc.fema.gov/portal/advanceSearch .	Apr. 12, 2024	230213
Massachusetts: Essex.	City of Gloucester (24-01-0023P).	The Honorable Greg Varga, Mayor, City of Gloucester, 9 Dale Avenue, Gloucester, MA 01930.	City Hall, 3 Pond Road, 2nd Floor, Gloucester, MA 01930.	https://msc.fema.gov/portal/advanceSearch .	Mar. 29, 2024	250082
Pennsylvania: Lancaster.	Township of East Hempfield (22-03-1093P).	Cindy Schweitzer, Manager, Township of East Hempfield, 1700 Nissley Road, Landisville, PA 17538.	Planning and Building Department, 1700 Nissley Road, Landisville, PA 17538.	https://msc.fema.gov/portal/advanceSearch .	Mar. 20, 2024	420548
Texas:						
Bexar	City of San Antonio (23-06-1883P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Public Works Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	https://msc.fema.gov/portal/advanceSearch .	Apr. 8, 2024	480045
Denton	Unincorporated areas of Denton County (23-06-1243P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Development Services Department, 3900 Morse Street, Denton, TX 76208.	https://msc.fema.gov/portal/advanceSearch .	Apr. 24, 2024	480774
Ellis	City of Grand Prairie (23-06-2587P).	The Honorable Ron Jensen, Mayor, City of Grand Prairie, P.O. Box 534045, Grand Prairie, TX 75053.	City Hall, 300 West Main Street, Grand Prairie, TX 75050.	https://msc.fema.gov/portal/advanceSearch .	Apr. 15, 2024	485472
Hays	Unincorporated areas of Hays County (23-06-1564P).	The Honorable Ruben Becerra, Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666.	Hays County Development Services Department, 2171 Yarrington Road, Suite 100, Kyle, TX 78640.	https://msc.fema.gov/portal/advanceSearch .	Apr. 11, 2024	480321
Midland	City of Midland (23-06-1759P).	The Honorable Lori Blong, Mayor, City of Midland, 300 North Loraine Street, Midland, TX 79701.	Engineering Department, 300 North Loraine Street, Midland, TX 79701.	https://msc.fema.gov/portal/advanceSearch .	Apr. 4, 2024	480477
Montgomery ...	City of Conroe (22-06-3014P).	The Honorable Jody Czajkoski, Mayor, City of Conroe, 300 West Davis Street, Conroe, TX 77301.	City Hall, 500 Metcalf Drive, Conroe, TX 77305.	https://msc.fema.gov/portal/advanceSearch .	Apr. 19, 2024	480484
Montgomery ...	Unincorporated areas of Montgomery County (22-06-3014P).	The Honorable Mark J. Keough, Montgomery County Judge, 501 North Thompson Street, Conroe, TX 77301.	Montgomery County Permitting Department, 501 North Thompson Street, Suite 100, Conroe, TX 77301.	https://msc.fema.gov/portal/advanceSearch .	Apr. 19, 2024	480483
Tarrant	City of Benbrook (23-06-1239P).	The Honorable Jason Ward, Mayor, City of Benbrook, 911 Winscott Road, Benbrook, TX 76126.	City Hall, 911 Winscott Road, Benbrook, TX 76126.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	480586
Tarrant	City of Fort Worth (23-06-1173P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	480596

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Tarrant	City of Fort Worth (23–06–1240P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	https://msc.fema.gov/portal/advanceSearch .	Mar. 25, 2024	480596
Tarrant	City of Fort Worth (23–06–1421P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault and Map Repository, 200 Texas Street, Fort Worth, TX 76102.	https://msc.fema.gov/portal/advanceSearch .	Apr. 8, 2024	480596
Tarrant	City of Lake Worth (23–06–1173P).	The Honorable Walter Bowen, Mayor, City of Lake Worth, 3805 Adam Grubb Street, Lake Worth, TX 76135.	City Hall, 3805 Adam Grubb Street, Lake Worth, TX 76135.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	480605
Tarrant	City of Mansfield (23–06–0492P).	The Honorable Michael Evans, Mayor, City of Mansfield, 1200 East Broad Street, Mansfield, TX 76063.	City Hall, 1200 East Broad Street, Mansfield, TX 76063.	https://msc.fema.gov/portal/advanceSearch .	Apr. 4, 2024	480606
Tarrant	Town of Lakeside (23–06–1173P).	The Honorable Patrick Jacob, Mayor, Town of Lakeside, 9830 Confederate Park Road, Lakeside, TX 76108.	Town Hall, 9830 Confederate Park Road, Lakeside, TX 76108.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	480604
Tarrant	Unincorporated areas of Tarrant County (23–06–1173P).	The Honorable Tim O'Hare, Tarrant County Judge, 100 East Weatherford Street, Suite 501, Fort Worth, TX 76196.	Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	480582
Utah: Weber	City of Ogden (23–08–0037P).	The Honorable Mike Caldwell, Mayor, City of Ogden, 2549 Washington Boulevard, Ogden, UT 84401.	City Hall, 2549 Washington Boulevard, Ogden, UT 84401.	https://msc.fema.gov/portal/advanceSearch .	Apr. 22, 2024	490189

[FR Doc. 2024–03263 Filed 2–15–24; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****[Docket ID FEMA–2024–0002; Internal Agency Docket No. FEMA–B–2406]****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 February 16, 2024.

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–2406, 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/prelim>

download 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.")

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Sherman County, Oregon and Incorporated Areas Project: 20-10-0028S Preliminary Date: August 12, 2022	
City of Grass Valley	City Hall, 109 Southwest 2nd Street, Grass Valley, OR 97029.
City of Moro	City Hall, 104 1st Street, Moro, OR 97039.
City of Rufus	City Hall, 304 West 2nd Street, Suite 100, Rufus, OR 97050.
City of Wasco	City Office, 1017 Clark Street, Wasco, OR 97065.
Unincorporated Areas of Sherman County	Sherman County Courthouse, 500 Court Street, Moro, OR 97039.

[FR Doc. 2024-03265 Filed 2-15-24; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7092-N-21]

Privacy Act of 1974; System of Records

AGENCY: Office of Housing, Single Family Insurance Operations Division, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of Housing and Urban Development (HUD), Office of Housing, Single Family Operations Division is modifying a system of records titled "Distributive Shares and Refund Subsystem (DSRS)". The DSRS serves as the Federal Housing Administration (FHA) repository for verifying mortgage insurance premium refunds and distributive share payments which are issued to eligible homeowners (mortgagors) who had an FHA mortgage insured loan. This system of records is being revised to make clarifying changes within: Authority for Maintenance of the System, System Location, Purpose of the System, Categories of Individuals

Covered by the System, Categories of Records in the System, Records Source Category, Routine Uses of Records Maintained, Retention and Disposal of Records, Record Access Procedures, Contesting Record Procedures, and Notification Procedures. The modifications are outlined in the **SUPPLEMENTARY INFORMATION** section.

DATES: Comments will be accepted on or before March 18, 2024. The SORN becomes effective immediately, while the routine uses become effective after the comment period immediately upon publication except for the routine uses, which will become effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number or by one of the following methods:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions provided on that site to submit comments electronically.

Fax: 202-619-8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410-0001.

Instructions: All submissions received must include the agency name and

docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov> including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410-0001; telephone number 202-708-3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: HUD, Single Family Insurance Operations Division (SFIOD), maintains the DSRS system. HUD is publishing this revised notice to reflect modifications to routine uses, and the system authorities. In accordance with the DSRS system of records, the SFIOD will implement a new Part B Online Application to provide homeowners with a convenient method to submit applications online. Additionally, administrative updates are being added to the remaining SORN

sections to reflect the system in its current state. The modification of the system of records will have no undue impact on the privacy of individuals and updates are consistent with the records collected.

The following are updates since the previous SORN publication:

- *Purpose of the System:* Added information pertaining to the new Part B Online Application to facilitate same-day request, homeowner application submission, and refund disbursement.

- *Record Source Category:* Added existing sources information for U.S. Department of Treasury, and New Part B Online Application web page.

- *Authority for Maintenance of the System:* Updated with existing authorities that permit the maintenance of the system's records by clarifying citations, correcting errors, and including relevant citations to the Code of Federal Register. Statutes and regulations are listed below.

- *Categories of Records in the System:* Updated the section with clarifying details and incorporated the Individual Tax Identification Number (ITIN), and related documents for certain non-residents and residents' aliens, spouses and dependents from other countries who do not have SSNs. The records are captured by records under "Identification and Verification" documents.

- *Routine Use of Records in System:* HUD will make modified disclosures from this system of records to authorized agencies and participants as described below. These modifications will enable HUD to issue payments and refunds and continue to test new technology. Additionally, the organization of the routine use section has changed from letters to numbers.

- Modified routine use (9)—(Changed from I) to refine and limit the scope of records shared for testing new technology to enhance program technology and services. This modification limits the scope of the prior record sharing activities.

- Modified routine use (6)—(Changed from F) to explain each Treasury disclosure type, the Treasury organization (The Bureau of the Fiscal Service), and additional details under Treasury collection services.

- *Records Retention and Disposition:* Updated this section by clarifying the general records schedules (GRS) by GRS Item Numbers, rather than down to the program level. Additionally, new GRS have been incorporated into the process.

SYSTEM NAME AND NUMBER:

Distributive Shares and Refund Subsystem (DSRS) HUD/HOU-03.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

National Center for Critical Information Processing and Storage, located in Mississippi and Virginia; the HUD Headquarter Building at 451 Seventh Street SW, Room 3238, Washington DC 20410-1000; Pyramid Systems at 2677 Prosperity Avenue, Fairfax Virginia 22031; M&M IT Solutions at 11750 Beltsville Drive, Beltsville MD, 20705-3194; Falon Sourcing Solutions at 9028 Prince William Street, Manassas, Virginia 20110-5664.

SYSTEM MANAGER(S):

Silas Vaughn, System Manager, Single Family Insurance Operations Division, Department of Housing and Urban Development, 451 Seventh Street SW, Second floor, Washington, DC 20410-0001; telephone number, 202-708-2438.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 203(a) of the National Housing Act of 1934 (12 U.S.C. 1709(a)); 24 CFR 203.35. Section 7(d) of the Department of Housing and Urban Development Act of 1965 (42 U.S.C. 3535(d)); 24 CFR 5.210; 24 CFR 200.1101. The Housing Community Development Act of 1987, 42 U.S.C. 3543(a). Section 4 of the Debt Collection Act of 1982, 31 U.S.C. 7701(b). Section 31001 of the Debt Collection Improvement Act of 1996, 31 U.S.C. 3711(g)(9). FHA Single Family Housing Policy Handbook 4000.1.

PURPOSES OF THE SYSTEM:

Distributive Shares and Refund Subsystem (DSRS) maintains detailed records for single family non-claim terminated case activities to ensure that the proper homeowner associated with the FHA guaranteed loan is identified. Upon non-claim termination (*i.e.*, prepayment, assignment, assumption, or refinancing), the borrower may be eligible for a refund of any unearned upfront mortgage insurance premium (UFMIP) paid at closing or a distributive share payment. The "Does HUD Owe You a Refund?" website is used in conjunction with DSRS to allow homeowners to determine if they are eligible for an upfront mortgage insurance premium refund or distributive share payment. In addition, DSRS utilizes the *Premium Refund Application Upload* web page component to provide another option for homeowners to securely send the required documents to HUD to complete the homeowner refund process, and the Part B Online Application web page to

support homeowners in securely submitting the application online, with the aim of enhancing HUD's responsiveness (Under Review). SFIOD staff can request disbursement of lender and homeowner refunds due, and DSRS will certify that the requests are valid.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Homeowners (Mortgagors) who had Federal Housing Administration (FHA) mortgage insured loans and may be eligible for a mortgage insurance premium refund or distributive share payment; (2) FHA approved Business Partners and Third-Party Representatives who are sources of mortgagor information, (3) Non-residents and residents' aliens, and dependents from other countries and (4) DSRS personnel (HUD users and authorized contractors) responsible for refund and share functions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name (Individual/Business), Social Security Number (SSN), Date of Birth, Phone Number, Address (Individual/Business), Email Address, and User ID, Related Premium Refund/Payment Correspondence (borrower name, address, email address, phone and fax number), including the homeowner representative and lender information, and Supporting Documentation (borrower identification and verification document copies): Birth, Death, Marriage, Religion, Civil Union, Naturalization, Citizenship Certificate, US Passport or Passport Card, Green Card, Change-of-Address (form CNL107 provided as proof), Driver's license, Dependent, Military, State, Federal ID with photo, or similar identification, Bank, Motor Vehicle, Mortgage, Credit Card, Tax, Utility, Doctor, Hospital Company Bill, Medicaid, Medicare Statement, Social Security Administration, Pension, Retirement Benefit Statement, Veteran Discharge or Separation Papers, Medical Card, W-2, 1099, DD-214 form (for SSN verification purposes), Pay Statement, Vehicle, Voters Registration, Legal documents (mortgage, deed, will, loan, rental contracts and statements, gender, name change) or similar document. Information on Supporting documents may include State were issued, SSN, Birthdate, Gender, Sex, Affiliation, Marital, Financial, Retirement, Pay, Employment, Medical, Account Number, Individual Tax Identification Number (ITIN), Employer Identification Number and related documents (IRS 147C EIN letter, IRS Payment coupon, IRS EIN Issuance Notice).

RECORD SOURCE CATEGORIES:

Homeowners, HUD employees and contractors, third party businesses, and authorized representatives of the homeowners that complete the form application for premium refund. Internal and External data exchanges from the following systems:

- Housing Office of Finance and Budget.
 - Single Family Insurance System (SFIS).
 - The Does HUD Owe You a Refund? " website.
 - Premium Refund Application Upload web page.
 - The Part B Online Application web page.
 - Automated Mailing System Generation.
- Office of the Chief Information Officer.
 - Digital Identity and Access Management System (DIAMS).
 - The Department of the Treasury, Bureau of the Fiscal Services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(1) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures, and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS's offering of mediation service to resolve disputes between persons making FOIA requests and administrative agencies.

(2) 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.

(3) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or other agreement for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(4) To contractors, grantees, experts, consultants and their agents, or others

performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

(5) To authorized requesters or third-party tracers who request access to Upfront Mortgage Insurance Premiums homeowner refund and distributive share payment information, when such information is unavailable on HUD's FOIA reading room or *Does HUD Owe You a Refund?* websites. This information is releasable under FOIA. Third party release of this material may require authorized consent of the homeowner to whom the records belong and must adhere to all HUD procedures prior to release.

(6) To the U.S. Department of the Treasury for disbursement, refund, and collection transactions:

(a) For upfront and monthly mortgage insurance premiums lender refunds; homeowner refunds; and distributive shares payments.

(b) For facilitating Treasury *Administrative Offset (Debt Collection)*: Offsets Federal tax refund payments and non-tax payments certified for disbursement to the debtor to recover a delinquent debt; and *Cross-servicing (Debt Collection)*: pursues recovery of delinquent debts on behalf of Federal agencies using debt collection tools authorized by statute, such as private collection agencies, administrative wage garnishment, or public dissemination of an individual's delinquent indebtedness; or any other legitimate debt collection purpose.

(7) To the general public when, after two-years of attempting to contact each unpaid mortgagor of their FHA insurance refund, the Department makes available a cumulative listing by state of any unpaid refund that remains unpaid. The information includes mortgagor full name(s), property address, insurance refund or share amount, insurance cancellation date and refund date, and loans FHA Case Number. This information is available to the public on HUD's refund database "*Does HUD Owe You A Refund?*". Individuals who search the database using an FHA Case Number or the name of the mortgagor can access this information before the two years of attempted contact has passed.

(8) To the recorders' offices for recording legal documents and responses to offsets (*i.e.*, child support) or other legal responses required during the servicing of the insured loan to allow HUD to release mortgage liens and

respond to bankruptcies or deaths of mortgagors to protect the interest of the Secretary of HUD.

(9) To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize relevant data for the purpose of testing new technology and systems designed to enhance program operations and performance.

(10) To another Federal agency or Federal entity, when HUD 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.

(11) To appropriate agencies, entities, and persons when: (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (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 HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws, when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(13) To a court, magistrate, administrative tribunal, or arbitrator in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations, or in connection with criminal law proceedings; when HUD determines that use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component

thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where HUD has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(14) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper and electronic.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Name, SSN, and Property Address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

General records are maintained for periods of Disposition is Temporary—1–6 years unless a longer retention period is deemed necessary for investigative purposes or business use. If necessary, Paper records are either burned or shredded, and electronic and media records are erased.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Administrative Controls: Backups Secured Off-Site, Methods to Ensure Only Authorized Personnel Access to PII, Periodic Security Audits, and Regular Monitoring of User's Security Practices.

Technical Controls: Encryption of Data at Rest, Firewall, Role-Based Access Controls, Virtual Private Network (VPN), Encryption of Data in Transit, Least Privilege Access, User Identification and Password, PIV Card, Intrusion Detection System (IDS).

Physical Safeguards: Combination locks, Key Cards, Security Guards, Identification badges, and all paper records that contain PII and sensitive information are locked in file rooms.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

CONTESTING RECORD PROCEDURES:

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16.8.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing Urban Development, 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR part 16.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Docket No. 87 FR 61618 (October 12, 2022), 81 FR 22292 (April 15, 2016), and 72 FR 40890 (July 25, 2007).

Ladonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024–03313 Filed 2–15–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7092–N–22]

Privacy Act of 1974; System of Records

AGENCY: Office of Housing, HUD.

ACTION: Notice of a rescindment of a system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), the Office of Housing, the Office of Lender Activities and Program Compliance (OLAPC), is issuing a public notice of its intent to rescind the Lender Electronic Assessment Portal (LEAP) because

information is not retrieve by personally identified information and therefor he system does not qualify as a Privacy Act System of Records.

DATES: Comments will be accepted on or before [March 18, 2024. This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov> including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

LaDonne White, Chief Privacy Officer, 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number (202) 708–3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: The Lender Electronic Assessment Portal (LEAP) is an internet-facing mechanism for organizations who wish to become approved Federal Housing Administration lenders. For prospective lenders, custom pages are presented as part of hud.gov to allow the lender to register interim credentials and respond to information requests. The only function accessible without authentication is registration and once registered the only function available is applying to be an approved lender. Office of Lender Activities and Program Compliance (OLAPC) staff access LEAP using internet Explorer. None of the functions are available to OLAPC personnel without authentication (against the HUD directory) and privileges (as responsibilities and

positions). These are enabled through configured definitions within the Siebel repository and administered data within the Siebel database. For example, a configured workflow might indicate that when an application is set to a specific status, an email should be sent to the lender. All components (except for very specific web pages) are maintained behind the HUD firewall and controls for securing those components are documented in the GSS. Records in the LEAP system have not run past its retention time. Per the Records Inventory Worksheet FY24, the LEAP Records are held for an indefinite period. Records in this system are housed in the LEAP database.

SYSTEM NAME AND NUMBER:

Lender Electronic Assessment Portal (LEAP), P278.

HISTORY:

The previously published notice in the **Federal Register** [Docket No. FR-5763-N-05], on May 27, 2014 at 79 FR 22826.

Ladonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024-03321 Filed 2-15-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7092-N-23]

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Procurement Officer, HUD.

ACTION: Notice of a rescindment of a system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), Office of Chief Procurement Officer (OCPO) is issuing this notice of its intent to rescind the HUD Integrated Acquisition Management System (HIAMS) because all data has migrated to the Enterprise Data Warehouse for decommissioning.

DATES: Comments will be accepted on or before March 18, 2024. This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions provided on that site to submit comments electronically.

Fax: 202-619-8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410-0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: The Privacy Office; 451 Seventh Street SW, Room 10139; Washington, DC 20410-0001; telephone number (202) 708-3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: HUD Integrated Acquisition Management System (HIAMS) was decommissioned and replaced by the US Department of Treasury's contract writing system Planning Tool for Resource Integration Synchronization and Management (PRISM) on October 1, 2014. Per the retention policy, HIAMS data/databases have been removed from all servers/networks.

SYSTEM NAME AND NUMBER:

HUD Integrated Acquisition Management System (HIAMS).

HISTORY:

The previously published notice in the **Federal Register** [Agency Docket Number FR-5478-N-05] at 76 FR 66949 (October 28, 2011).

Ladonne L. White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024-03320 Filed 2-15-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7086-N-04]

60-Day Notice of Proposed Information Collection: Rehabilitation Mortgage Insurance Program Section 203(k), OMB Control No.: 2502-0527

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* April 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 60-day Review—Open for Public Comments" or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410-5000; telephone 202-402-3577 (this is not a toll-free number) or email: PaperworkReductionActOffice@hud.gov.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email Colette Pollard at Colette.Pollard@hud.gov or telephone (202) 402-3400 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

relay-service-trs. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Rehabilitation Mortgage Insurance Underwriting Program Section 203(k).

OMB Approval Number: 2502–0527.

OMB Expiration Date: August 31, 2024.

Type of Request: Extension of currently approved collection.

Form Number: HUD–92700–A, HUD–9746–A.

Description of the need for the information and proposed use: This request for OMB review involves an extension request for information collected under OMB Approval Number 2502–0527 for lenders that originate and service section 203(k) mortgages. The section 203(k) program requires mortgagees to collect information about the scope of repair and improvement work, its cost, and control of escrow funds to pay for the improvements as they are completed. This program operates in conjunction with FHA's underwriting standards and systems for all section 203(b) loans as documented in OMB Control Numbers 2502–0059 & 2502–0556. Per the existing collection, there are 1,041 respondents made up of participating lenders and 203(k) Consultants.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 1,041.

Estimated Number of Responses: 103,317.

Frequency of Response: On occasion (Once per loan).

Average Hours per Response: 0.89.

Total Estimated Burden: 92,269.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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;

(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 those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2024–03314 Filed 2–15–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7086–N–07]

60-Day Notice of Proposed Information Collection: Mortgage Record Change, OMB Control No.: 2502–0422

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* April 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 60-day Review—Open

for Public Comments” or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–3577 (this is not a toll-free number) or email: PaperworkReductionActOffice@hud.gov.

FOR FURTHER INFORMATION CONTACT:

Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at Colette.Pollard@hud.gov or telephone (202) 402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Mortgage Record Change.

OMB Approval Number: 2502–0422.

OMB Expiration Date: 7/31/2024.

Type of Request: Extension of currently approved collection.

Form Number: The Mortgage Record Change is submitted electronically through FHA Connection.

Description of the need for the information and proposed use: In accordance with 23 CFR 203.502(a), servicing of insured mortgages must be performed by a mortgagee that is approved by HUD to service insured mortgages. The Mortgage Record Change information is used by FHA-approved mortgagees to comply with HUD requirements for reporting the sale of a mortgage between investors, the transfer of the mortgage servicing responsibility, and/or a change of mortgagor, as appropriate.

Information collection	Number of respondents	Frequency of response	Total annual responses	Hours per response	Total annual hours
Mortgage Record Change	10,000	Varies	3,263,703	0.1	326,370
Totals	10,000	3,263,703	326,370

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

- (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;
- (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 those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.
- HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,
General Deputy Assistant Secretary for Housing.

[FR Doc. 2024-03315 Filed 2-15-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-IA-2024-0028; FXIA1671090000-245-FF09A30000]

Endangered Species; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued permits to conduct certain activities with endangered species. We issue these permits under the Endangered Species Act.

FOR FURTHER INFORMATION CONTACT: Timothy MacDonald, by phone at 703-358-2185 or via email at DMAFR@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have issued permits to conduct certain activities with endangered and

threatened species in response to permit applications that we received under the authority of section 10(a)(1)(A) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*)

After considering the information submitted with each permit application and the public comments received, we issued the requested permits subject to certain conditions set forth in each permit. For each application for an endangered species, we found that (1) the application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

Availability of Documents

The permittees' original permit application materials, along with public comments we received during public comment periods for the applications, are available for review. To locate the application materials and received comments, go to <https://www.regulations.gov> and search for the appropriate permit number (*e.g.*, PER12345) provided in the following table.

Permit No.	Applicant	Permit issuance date
PER2499014	Smithsonian National Zoo and Conservation Biology Institute	August 1, 2023.
PER4095187	Smithsonian National Zoo and Conservation Biology Institute	October 2, 2023.
PER4361497	Disney's Animal Kingdom	November 14, 2023.
PER2475594	Sedgwick County Zoo	December 14, 2023.
PER5322138	Ryder Scientific, R.L.L.P., dba Ryder Scientific	December 18, 2023.
PER0070277	Kimberly Ange-can Heugten	December 19, 2023.
PER5068413	Rancho Santa Ana Botanic Garden	January 4, 2024.
PER4743691	Los Angeles Zoo	January 18, 2024.
PER5156259	Miami-Dade Zoological Park and Gardens	January 23, 2024.
PER5156944	Midwestern University	January 30, 2024.

Authority

We issue this notice under the authority of the Endangered Species

Act, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Timothy MacDonald,
Government Information Specialist, Branch of Permits, Division of Management Authority.

[FR Doc. 2024-03280 Filed 2-15-24; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500178029]

Filing of Plats of Survey: Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), Alaska State Office, Anchorage, Alaska. The surveys, which were executed at the request of the BLM, are necessary for the management of these lands.

DATES: The BLM must receive protests by March 18, 2024.

ADDRESSES: You may buy a copy of the plats from the BLM Alaska Public Information Center, 222 W 7th Avenue, Mailstop 13, Anchorage, AK 99513. Please use this address when filing written protests. You may also view the plats at the BLM Alaska Public Information Center, Fitzgerald Federal Building, 222 W 7th Avenue, Anchorage, Alaska, at no cost.

FOR FURTHER INFORMATION CONTACT: Thomas B. O'Toole, Chief, Branch of Cadastral Survey, Alaska State Office, Bureau of Land Management, 222 W 7th Avenue, Anchorage, AK 99513; 907-271-4231; totoole@blm.gov. People who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the BLM during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Copper River Meridian, Alaska

T. 13 S., R. 5 E., accepted January 4, 2024.
T. 16 S., R. 1 W., accepted January 4, 2024.
U.S. Survey No. 14621, accepted January 5, 2024, situated in T. 8 S., R. 8 W.
U.S. Survey No. 14637, accepted January 5, 2024, situated in T. 11 N., R. 3 W.
U.S. Survey No. 14640, accepted January 30, 2024, situated in T. 25 N., R. 13 E.
U.S. Survey No. 14641, accepted January 30, 2024, situated in T. 23 N., R. 12 E.

Fairbanks Meridian, Alaska

U.S. Survey No. 14552, accepted February 1, 2024, situated in T. 6 N., R. 3 W.

Seward Meridian, Alaska

T. 22 N., R. 67 W., accepted February 1, 2024.
T. 20 N., R. 68 W., accepted February 1, 2024.
T. 21 N., R. 68 W., accepted February 1, 2024.
U.S. Survey No. 10050, accepted January 5, 2024, situated in T. 12 N., R. 6 W.

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the State Director for the BLM in Alaska. The protest may be filed by mailing to BLM State Director, Alaska State Office, Bureau of Land Management, 222 W 7th Avenue, Anchorage, AK 99513 or by delivering it in person to BLM Alaska Public

Information Center, Fitzgerald Federal Building, 222 W 7th Avenue, Anchorage, Alaska. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. You must file the notice of protest before the scheduled date of official filing for the plat(s) of survey being protested. The BLM will not consider any notice of protest filed after the scheduled date of official filing. A notice of protest is considered filed on the date it is received by the State Director for the BLM in Alaska during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director for the BLM in Alaska within 30 calendar days after the notice of protest is filed.

If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personally identifiable information in a notice of protest or statement of reasons, you should be aware that the documents you submit, including your personally identifiable information, may be made publicly available in their entirety at any time. While you can ask the BLM to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. chap. 3.

Thomas B. O'Toole,
Chief Cadastral Surveyor, Alaska.

[FR Doc. 2024-03326 Filed 2-15-24; 8:45 am]

BILLING CODE 4331-10-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NV_FRN_MO# 4500177747]

Notice of Public Meeting: Sierra Front-Northern Great Basin Resource Advisory Council

AGENCY: Bureau of Land Management, Department of Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory

Committee Act of 1972, the U.S. Department of the Interior's Bureau of Land Management (BLM) Sierra Front-Northern Great Basin Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Sierra Front-Northern Great Basin RAC will hold an in-person meeting with a virtual participation option on Thursday, April 11, 2024. The RAC will also host a field tour on Friday, April 12. The meeting will be held from 8 a.m. to 5 p.m. Pacific Time (PT) and may end earlier or later depending on the needs of group members. The field tour will begin at 8 a.m. and conclude at approximately 1 p.m. PT.

ADDRESSES: The meeting will be held at the BLM Carson City District Office, 5665 Morgan Mill Road, Carson City, Nevada 89701. Individuals that prefer to participate in the April 11 meeting virtually must register by visiting the RAC's web page at least one week in advance of the meeting at <https://www.blm.gov/get-involved/resource-advisory-council/near-me/nevada>. Individuals participating in the April 12 field tour will meet at 8 a.m. PT at the Carson City District Office (5665 Morgan Mill Road) and travel to the Naval Air Station Fallon area east of Fallon, Nevada.

Written comments can be mailed to: BLM Carson City District Office, Attn: Lisa Ross, RAC Coordinator; 5665 Morgan Mill Road, Carson City, NV 89701. Comments can also be submitted by email to lross@blm.gov with the subject line: BLM Sierra Front-Northern Great Basin RAC.

FOR FURTHER INFORMATION CONTACT: Lisa Ross, RAC Coordinator, by telephone at (775) 885-6107, or by email at lross@blm.gov. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The 15-member BLM Sierra Front-Northern Great Basin RAC serves in an advisory capacity concerning issues relating to land use planning and the management of the public land resources located within the BLM's Elko, Winnemucca, and Carson City Districts. Meetings are open to the public in their entirety and a public comment period will be held near the end of the meeting.

Agenda items for the April 11 meeting include district updates; discussion

regarding the Sand Mountain Recreation Area, Mining Law, and Tribal Consultation Process; and an overview of the Utility-Scale Solar Energy Development Programmatic Environmental Impact Statement. The field tour will offer participants the opportunity to view and discuss resource/mitigation issues associated with the proposed expansion of Naval Air Station Fallon and the Sand Mountain Recreation Area. The field tour will conclude at approximately 1 p.m. PT. Members of the public are welcome on field tours but must provide their own transportation and meals.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

The final meeting agenda will be available two weeks in advance of the meeting on the RAC's web page at <https://www.blm.gov/get-involved/resource-advisory-council/near-me/nevada>.

Interested persons may make verbal presentations to the RAC during the meeting or file written statements. Such requests should be made to RAC Coordinator Lisa Ross prior to the public comment period. Depending on the number of people who wish to speak, the time for individual comments may be limited.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1784.4-2)

Kimberly D. Dow,

Designated Federal Officer, BLM Carson City District Manager.

[FR Doc. 2024-03143 Filed 2-15-24; 8:45 am]

BILLING CODE 4331-21-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_UT_FRN_MO4500176456]

Notice of Public Meeting, Bears Ears National Monument Advisory Committee, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act, as amended, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM's) Bears Ears National Monument Advisory Committee will meet as indicated below.

DATES: The Bears Ears National Monument Advisory Committee will hold three in-person meetings with virtual participation options in 2024. These meetings are open to the public. The meeting dates are March 27, 2024, August 8, 2024, and December 9, 2024.

ADDRESSES: The meetings will be held in-person at the Hideout Community Center located at 648 South Hideout Way, Monticello, Utah 84535. The meetings will take place from 9 a.m. to approximately 4 p.m. Agendas and virtual meeting access information will be announced on the Bears Ears National Monument Advisory Committee web page 30 days before the meeting at www.blm.gov/benm-mac.

FOR FURTHER INFORMATION CONTACT:

Rachel Wootton, Canyon Country District Public Affairs Officer, P.O. Box 7, Monticello, Utah 84535, via email with the subject line "BENM MAC" to blm_ut_mt_mail@blm.gov, or by calling the Monticello Field Office at (435) 587-1500. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Presidential Proclamation 9558 and Presidential Proclamation 10285 established the Bears Ears National Monument Advisory Committee to provide advice and information to the Secretary of the Interior through the Director of the BLM, and to the Secretary of the U.S. Department of Agriculture (USDA) through the Chief of

the USDA Forest Service, to consider for managing the Bears Ears National Monument. The 15-member Committee represents a wide range of interests including State and local government, paleontological and archaeological expertise, the conservation community, livestock grazing permittees, Tribal members, developed and dispersed recreation interests, private landowners, local business owners, and the public at large.

Planned agenda items for the March meeting include an overview of the planning efforts to-date, discussion of management alternatives included in the draft Bears Ears National Monument Resource Management Plan, ongoing draft Resource Management Plan public comment period, and general management and administrative updates. Planned agenda items for the August meeting include an overview of the planning efforts to-date, discussion of management alternatives included in the draft Bears Ears National Monument Resource Management Plan, upcoming steps in the planning process including proposed RMP, protest period, and governor's consistency review, and general management and administrative updates. Planned agenda items for the December meeting include planning efforts to-date, discussion of the proposed Bears Ears National Monument Resource Management Plan, ongoing Resource Management Plan protest period and governor's consistency review and general management and administrative updates.

A public comment period will be offered during each meeting at 1:15 p.m. Depending on the number of people wishing to comment and the time available, the time for individual comments may be limited. Written comments may also be sent to the Monticello Field Office at the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. All comments received prior to the meeting will be provided to the Committee.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed under **FOR FURTHER INFORMATION CONTACT**, at least seven days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware your entire comment—including your

personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

Detailed minutes for Bears Ears National Monument Advisory Committee meetings will be maintained in the Canyon Country District Office and will be available for public inspection and reproduction during regular business hours within 90 days following the meeting. Minutes will also be posted to the Committee's web page.

Authority: 5 U.S.C. Ch. 10.

Gregory Sheehan,

State Director.

[FR Doc. 2024–03286 Filed 2–15–24; 8:45 am]

BILLING CODE 4331–25–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–37326;
PPWOCRADIO, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before January 27, 2024, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by March 4, 2024.

ADDRESSES: Comments are encouraged to be submitted electronically to *National Register Submissions@nps.gov* with the subject line “Public Comment on <property or proposed district name, (County) State>.” If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov*, 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the

National Park Service before January 27, 2024. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

GEORGIA

Richmond County

Augusta Warehouse and Compress Company,
1812 Slaton Street, Augusta, SG100010016

INDIANA

Carroll County

South Delphi Historic District, Roughly bounded by the north boundary of Riley Park on the north, Prince William Road on the northeast, the alley south of Summit Street on the southeast, and Wabash Street and the west boundary of Riley Park on the south and southwest, Delphi,
SG100010027

Fulton County

Akron Historic District, Roughly both sides of Rochester Street between Marcus Street to the west and State Road 14 North to the east and both sides of Mishawaka Street between North Street to the north and Rochester Street to the south, Akron,
SG100010028

Jackson County

Crothersville Independent Order of Oddfellows (IOOF) Lodge, 121 East Howard Street, Crothersville, SG100010030

Marion County

United States Corrugated-Fibre Box Company Plant, 1411 Roosevelt Avenue, Indianapolis, SG100010031

Shelby County

Messick Masonic Temple, 519 South Harrison Street, Shelbyville, SG100010029

KANSAS

Douglas County

First Presbyterian Church, 2415 Clinton Parkway, Lawrence, SG100010035

MISSISSIPPI

Quitman County

Marks Downtown Historic District, Main, Chestnut, Peach, Maple, Poplar, Walnut, Third, First, and Lamar/Pecan Streets, Marks, SG100010020

NEW YORK

Columbia County

Philmont Historic District, Ark St., Band St., Block St., Canal St., Church St., Columbia Ave., Eagle St., Ellsworth St., Elm St., Garden St., Main St., Maple Ave., Philmont, SG100010025

Monroe County

Azalea-Highland Park Terrace Historic District, Portions of Meadowbrook, Azalea, Laney, Arbor Roads and Highland & Elmwood Avenues, Rochester, SG100010023

Onondaga County

Marshall & Son Warehouse, 1 Webster's Landing, Syracuse, SG100010024

OHIO

Lucas County

Spicer Manufacturing Building, 4100 Bennett Road, Toledo, SG100010036

Muskingum County

New Concord-Union High School, 4 Stormont Street, New Concord, SG100010018

PUERTO RICO

San Juan Municipality

Casa Gonzalez Cuyar, #225 Calle del Parque, San Juan, SG100010033

TEXAS

Harris County

Sills Building, 5804 Canal Street, Houston, SG100010026

Travis County

West Downtown Austin Historic District, Roughly bounded by W. 15th Street {north}, San Antonio/Nueces Streets (east), W. 7th Street {south}, and West Avenue/Shoal Creek (west), Austin, SG100010021

A request for removal has been made for the following resource(s):

INDIANA

Boone County

Scotland Bridge, Lost Rd. (Co. Rd. 200 E) over Sugar Cr., Mechanicsburg vicinity, OT94000228

Additional documentation has been received for the following resource(s):

HAWAII

Honolulu County

St. Andrew's Cathedral (Additional Documentation), Beretania St. (Queen Emma Sq.), Honolulu, AD73000663

TENNESSEE**Bedford County**

Bedford County Jail (Additional Documentation), 210 N. Spring Street, Shelbyville, AD75001728

River Side Farmhouse (Additional Documentation), 497 Shofner Rd., Shelbyville vicinity, AD97001501

De Kalb County

Alexandria Cemeteries Historic District (Additional Documentation), (Rural African-American Churches in Tennessee MPS), Cemetery St., Alexandria, AD02000584

Hamilton County

Brabson House (Additional Documentation), 407 E. 5th St., Chattanooga, AD73001772
Old Post Office (Additional Documentation), 31 E. 11th Street, Chattanooga, AD73001777

James County Courthouse (Additional Documentation), 9508 Church Street, Ooltewah, AD76001782

Trigg-Smartt Building (Additional Documentation), 701—707 Broad St., Chattanooga, AD86001383

Knox County

Seven Islands Methodist Church (Additional Documentation), (Knoxville and Knox County MPS), 8100 Seven Islands Rd., Knoxville vicinity, AD97000244

Sevier County

Harrisburg Covered Bridge (Additional Documentation), S of Harrisburg off U.S. 411 over East Fork of Little Pigeon River, Harrisburg vicinity, AD75001777

Weakley County

Sims, Capt. William, House (Additional Documentation), 1912 Liberty Road, Greenfield vicinity, AD82004066

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

*Chief, National Register of Historic Places/
National Historic Landmarks Program.*

[FR Doc. 2024-03244 Filed 2-15-24; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-NRNL-DTS#-37389;
PPWOCRADIO, PCU00RP14.R50000]

**National Register of Historic Places;
Notification of Pending Nominations
and Related Actions**

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before February 3, 2024, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by March 4, 2024.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line “Public Comment on <property or proposed district name, (County) State>.” If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov*, 202-913-3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before February 3, 2024. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers.

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

ARIZONA**Pinal County**

Randolph Community Historic District, Generally bounded by Highway 287, East Randolph Rd., East Kleck Rd., and Union Pacific Railroad Right-of-Way, Coolidge, SG100010053

FLORIDA**Putnam County**

First Congregational Church of Interlachen, 415 Washington Street, Interlachen, SG100010040

LOUISIANA**Acadia Parish**

Shrine of Our Mother of Mercy Catholic Church and School, 707 Lyman Avenue, Rayne, SG100010045

Orleans Parish

Joe Victor's Saloon and Grocery, 1534 St. Louis Street, New Orleans, SG100010046

Rapides Parish

Old Pineville Town Hall, 731 Main Street, Pineville, SG100010047

St. Martin Parish

Emile Bergeron Farmstead, 4507-C Main Highway, Breaux Bridge, SG100010048

OHIO**Franklin County**

Columbus Carriage Manufacturing Co.—Seagrave Co. Buildings
2000–2050 S High St., Columbus, SG100010052

Hamilton County

La Ventura Apartments, (Apartment Buildings in Ohio Urban Centers, 1870–1970 MPS), 700 Chalfonte Place, Cincinnati, MP100010054

OKLAHOMA**Jackson County**

Altus Junior College Library, 221 North Park Lane, Altus, SG100010049

Tulsa County

Blevins, Charles and Bertha. House, 1838 North Norfolk Avenue, Tulsa, SG100010050

TENNESSEE**Shelby County**

Cherokee Arms, (Residential Resources of Memphis MPS), 1508 Madison Avenue, Memphis, MP100010039

UTAH**Salt Lake County**

Walker, George and Lida, House, 2480 E Walker Ln Holladay, UT 84117-7718, Holladay, SG100010060

Utah County

Bullock, Edward “Bob” and Mertilla, House, 1548 North Locust Lane, Provo, SG100010057

VERMONT**Grand Isle County**

South Hero Village Historic District, US Route 2, Hill Road, South Street, South Hero, SG100010055

VIRGINIA**Albemarle County**

Scottsville Tire Cord Plant, 800 Bird Street, Scottsville, SG100010041

Augusta County

Dutch Hollow Hanger Cemetery, 911 Wagon Shop Road, Middlebrook, SG100010042
A request to move has been received for the following resource(s):

LOUISIANA**St. John The Baptist Parish**

Southern Pacific Steam Locomotive #745,
Timbermill Museum, Garysville,
MV98001077

Additional documentation has been
received for the following resource(s):

TENNESSEE**Bradley County**

Centenary Avenue Historic District
(Additional Documentation), Roughly
bounded by 8th, Harle, 13th and Ocoee
Sts., Cleveland, AD93000172

Davidson County

Inglewood Place Historic District (Additional
Documentation), Golf, Greenfield, Howard,
Jakes, Katherine, Kennedy, Kirkland,
McChesney, Riverside, Shelton & Stratford
Aves., Nashville, AD16000117
Cane Ridge Cumberland Presbyterian Church
(Additional Documentation), 13412 Old
Hickory Blvd., Antioch vicinity,
AD76001770

Fayette County

Petersburg Historic District (Additional
Documentation), Roughly bounded by
Church, Railroad, Gaunt Sts., and TN 50,
Petersburg, AD85002753

Smith County

Smith County Courthouse, 211 Main Street
North, Carthage, AD79002483

VIRGINIA**Fairfax INDEPENDENT CITY**

City of Fairfax Historic District (Additional
Documentation), Jct. of VA 236 and VA
123, Fairfax (Independent City),
AD87001432

Fauquier County

Warrenton Historic District (Additional
Documentation), Roughly Main, Waterloo,
Alexandria, Winchester, Culpeper, High,
Falmouth, Lee, and Horner Sts.,
Warrenton, AD83004243

Authority: Section 60.13 of 36 CFR
part 60.

Sherry A. Frear,

*Chief, National Register of Historic Places/
National Historic Landmarks Program.*

[FR Doc. 2024–03245 Filed 2–15–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS–IMR–AMCH–NPS0036797; ACCT
Number: PPIMAMCH00//
PPMPSAS1Z.Y00000]

Amache National Historic Site

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: As authorized by the Amache
National Historic Site Act, the National

Park Service announces that the
Secretary of the Interior has established,
in the State of Colorado, the Amache
National Historic Site as a unit of the
National Park System.

FOR FURTHER INFORMATION CONTACT:

Brian Carlstrom, Deputy Regional
Director, NPS, Intermountain Region at
720–616–9266.

ADDRESSES: A color version and more
detailed area maps depicting the
boundary are available here: [https://
www.nps.gov/amch/planyourvisit/
maps.htm](https://www.nps.gov/amch/planyourvisit/maps.htm).

SUPPLEMENTARY INFORMATION: On March
18, 2022, President Biden signed into
law Public Law 117–106, which
provides for the designation of the
Granada Relocation Center in Prowers
County, Colorado, as Amache National
Historic Site. Amache was one of 10
incarceration camps established by the
War Relocation Authority during World
War II (WWII) to unjustly incarcerate
Japanese Americans who were forcibly
removed from their communities on the
West Coast under the provisions of
Executive Order 9066.

The statute provides that Amache
National Historic Site shall be
established as a unit of the National
Park System once the Secretary
determines that a sufficient quantity of
land, or interests in land, has been
acquired to constitute a manageable
park unit, and that the Secretary must
publish notice of such establishment in
the **Federal Register**.

The National Park Service has
acquired 410 acres within the proposed
historic site boundary, encompassing
the core of the former built-up area of
Amache. On February 9, 2024, the
Secretary of the Interior signed a
Decision Memorandum determining
that a sufficient quantity of land, or
interests in land, had been acquired to
constitute a manageable park unit. With
the signing of this Decision
Memorandum by the Secretary and the
publication of this notice in the **Federal
Register**, Amache National Historic Site
is established.

Charles F. Sams III,

Director, National Park Service.

[FR Doc. 2024–03250 Filed 2–15–24; 8:45 am]

BILLING CODE P

**INTERNATIONAL TRADE
COMMISSION**

[Investigation No. 731–TA–1189 (Second
Review)]

**Large Power Transformers From South
Korea; Scheduling of a Full Five-Year
Review**

AGENCY: United States International
Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives
notice of the scheduling of a full review
pursuant to the Tariff Act of 1930 (“the
Act”) to determine whether revocation
of the antidumping duty order on large
power transformers from South Korea
would be likely to lead to continuation
or recurrence of material injury within
a reasonably foreseeable time.

DATES: February 12, 2024.

FOR FURTHER INFORMATION CONTACT:

Kristina Lara (202–205–3386), Office of
Investigations, U.S. International Trade
Commission, 500 E Street SW,
Washington, DC 20436. Hearing-
impaired persons can obtain
information on this matter 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 ([https://
www.usitc.gov](https://www.usitc.gov)). The public record for
this review may be viewed on the
Commission’s electronic docket (EDIS)
at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On December 5, 2023,
the Commission determined that
responses to its notice of institution of
the subject five-year review were such
that a full review should proceed (88 FR
87457, December 18, 2023); accordingly,
a full review is being scheduled
pursuant to section 751(c)(5) of the
Tariff Act of 1930 (19 U.S.C. 1675(c)(5)).
A record of the Commissioners’ votes,
the Commission’s statement on
adequacy, and any individual
Commissioner’s statements are available
from the Office of the Secretary and at
the Commission’s website.

*Participation in the review and public
service list.*—Persons, including
industrial users of the subject
merchandise and, if the merchandise is
sold at the retail level, representative
consumer organizations, wishing to
participate in this review as parties
must file an entry of appearance with
the Secretary to the Commission, as

provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the review will be placed in the nonpublic record on June 3, 2024, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold an in-person hearing in connection with the review beginning at 9:30 a.m. on June 20, 2024. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission by no later than 5:15 p.m. on June 12, 2024. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to

conduct the review, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID-19 test result may be submitted by 3 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at <https://www.usitc.gov/calendarpad/calendar.html>.

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on June 18, 2024. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than 4 p.m. on June 18, 2024. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is 5:15 p.m. on June 11, 2024. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is 5:15 p.m. on June 28, 2024. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review by no later than 5:15 p.m. on June 28, 2024. On July 24, 2024, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information by no later than 5:15 p.m. on July 26, 2024, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6,

207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: February 13, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-03246 Filed 2-15-24; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-703 and 731-TA-1661-1663 (Preliminary)]

Glass Wine Bottles From Chile, China, and Mexico

Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of glass wine bottles from Chile, China, and Mexico, provided for in subheading 7010.90.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value ("LTFV") and imports of the subject merchandise from

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

China that are alleged to be subsidized by the government of China.²

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce ("Commerce") of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Any other party may file an entry of appearance for the final phase of the investigations after publication of the final phase notice of scheduling. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations. As provided in section 207.20 of the Commission's rules, the Director of the Office of Investigations will circulate draft questionnaires for the final phase of the investigations to parties to the investigations, placing copies on the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>), for comment.

Background

On December 29, 2023, the U.S. Glass Producers Coalition, which is comprised of Ardagh Glass Inc., Indianapolis, Indiana and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, Pittsburgh, Pennsylvania filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of glass wine bottles from China

and LTFV imports of glass wine bottles from Chile, China, and Mexico. Accordingly, effective December 29, 2023, the Commission instituted countervailing duty investigation No. 701-TA-703 and antidumping duty investigation Nos. 731-TA-1661-1663 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of January 5, 2024 (89 FR 809). The Commission conducted its conference on January 19, 2024. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on February 12, 2024. The views of the Commission are contained in USITC Publication 5496 (February 2024), entitled *Glass Wine Bottles from Chile, China, and Mexico: Investigation Nos. 701-TA-703 and 731-TA-1661-1663 (Preliminary)*.

By order of the Commission.

Issued: February 12, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-03227 Filed 2-15-24; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On February 13, 2024, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of New Mexico in the lawsuit entitled *United States of America and New Mexico Environment Department v. Apache Corporation*, Civil Action No. 24-cv-00149.

In this action, the United States, on behalf of the U.S. Environmental Protection Agency, and the New Mexico Environment Department filed a complaint alleging that Apache Corporation ("Defendant") violated the Clean Air Act, the New Mexico Air Quality Control Act, their implementing regulations, and the Texas State Implementation Plan at 23 of Defendant's oil and natural gas production facilities in New Mexico and Texas by failing to comply with

requirements of the Federal New Source Performance Standards set forth at 40 CFR part 60, subpart OOOO and OOOOa, and failing to operate its facilities in accordance with applicable permits, namely, the New Mexico General Construction Permit for Oil and Gas Facilities and the Texas Commission on Environmental Quality Permit by Rule and Standard Permit. The complaint seeks an Order enjoining Defendant from further violating applicable requirements and requiring Defendant to remedy, mitigate, and offset the harm to public health and the environment caused by the violations and to pay a civil penalty.

Under the proposed settlement, Defendant agrees to pay a civil penalty of \$4,000,000 and to perform a project that will offset the excess emissions resulting from the violations. In addition, the settlement requires the Defendant to ensure ongoing compliance with all applicable regulatory requirements at 422 of its oil and natural gas production facilities in New Mexico and Texas. Specifically, the settlement requires the Defendant to undertake a field survey to identify and remedy any compromised equipment, to undertake a design analysis to ensure adequate design and sizing of the vapor control system, to install and operate extensive monitoring systems, to implement a robust inspection and maintenance program, and to hire an independent third party to verify compliance.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and New Mexico Environment Department v. Apache Corporation*, D.J. Ref. No. 90-5-2-1-12523. 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.

Any comments submitted in writing may be filed by the United States in whole or in part on the public court docket without notice to the commenter. During the public comment period, the proposed consent decree may be

² 89 FR 4905 and 89 FR 4911 (January 25, 2024).

examined and downloaded at this Justice Department website: <http://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing the proposed consent decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024-03293 Filed 2-15-24; 8:45 am]

BILLING CODE 4410-15-P

NUCLEAR REGULATORY COMMISSION

713th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on March 6–8, 2024. The Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MS Teams or via phone at 301-576-2978, passcode 734707940#. A more detailed agenda including the MSTeams link may be found at the ACRS public website at <https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html>. If you would like the MSTeams link forwarded to you, please contact the Designated Federal Officer as follows: Quynh.Nguyen@nrc.gov, or Lawrence.Burkhart@nrc.gov.

Wednesday, March 6, 2024

8:30 a.m.–8:35 a.m.: *Opening Remarks by the ACRS Chair (Open)*—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: *Draft Final Branch Technical Position (BTP) 7-19, Revision 9, “Guidance for Evaluation of Diversity and Defense-in-Depth to Address Common Cause Failure Due to Latent Design Effects in Digital Computer-Based Instrumentation and Control Systems” (Open)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

10:30 a.m.–1:00 p.m.: *Committee Deliberation on Draft Final BTP 7-19, Revision 9 (Open)*—The Committee will

have deliberations regarding the subject topic.

1:00 p.m.–3:00 p.m.: *Review of NRC Research Program—Artificial Intelligence and Machine Learning in Non-Destructive Examination and In-Service Inspection Activities (Open)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

3:00 p.m.–6:00 p.m.: *Preparation of Reports (Open)*—The Committee will continue its discussion of proposed ACRS reports.

Thursday, March 7, 2024

8:30 a.m.–10:30 a.m.: *Planning and Procedures Session/Future ACRS Activities/Reconciliation of ACRS Comments and Recommendations/Preparation of Reports (Open/Closed)*—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports as determined by the Chairman. [NOTE: Pursuant to 5 U.S.C. 552b(c)(2), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS.]

[NOTE: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

10:30 a.m.–2:00 p.m.: *Review of NRC Research Program—High Energy Arc Fault (Open)*—The Committee will have presentations and discussion with the NRC staff regarding the subject topic.

2:00 p.m.–6:00 p.m.: *Preparation of Reports (Open)*—The Committee will continue its discussion of proposed ACRS reports.

Friday, March 8, 2024

8:30 a.m.–6:00 p.m.: *Preparation of Reports (Open)*—The Committee will continue its discussion of proposed ACRS reports.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the Designated Federal Officer (Telephone: 301-415-5844, Email: Quynh.Nguyen@nrc.gov), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the

meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with subsection 10(d) of Public Law 92-463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at pdr.resource@nrc.gov, or by calling the PDR at 1-800-397-4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at <https://www.nrc.gov/reading-rm/adams.html> or <https://www.nrc.gov/reading-rm/doc-collections/#ACRS/>.

Dated: February 13, 2024.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2024-03236 Filed 2-15-24; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2023-0099]

Information Collection: Material Control and Accounting of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, “Material Control and Accounting of Special Nuclear Material.”

DATES: Submit comments by March 18, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0099 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2023–0099.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML23347A096 and ML23184A055.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Clearance Officer, David C. Cullison, Office of the Chief Information Officer,

U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, “Material Control and Accounting of Special Nuclear Material.” The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on October 2, 2023, 88 FR 67827.

1. *The title of the information collection:* 10 CFR part 74, Material Control and Accounting of Special Nuclear Material.
2. *OMB approval number:* 3150–0123.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* Submission of

fundamental nuclear material control plans is a one-time requirement which has been completed by all current licensees as required. However, licensees may submit amendments or revisions to the plans as necessary. Reports are submitted as events occur.

6. *Who will be required or asked to respond:* Persons licensed under part 74 of title 10 of the *Code of Federal Regulations* (10 CFR), who possess and use certain forms and quantities of special nuclear material (SNM).

7. *The estimated number of annual responses:* 183.

8. *The estimated number of annual respondents:* 163.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 9,439 hours (939 reporting + 8,500 recordkeeping).

10. *Abstract:* 10 CFR part 74 establishes requirements for material control and accounting of SNM, and specific performance-based regulations for licensees authorized to possess, use, or produce strategic SNM, SNM of moderate strategic significance, or SNM of low strategic significance. The information is used by the NRC to make licensing and regulatory determinations concerning material control of SNM and to satisfy obligations of the United States to the International Atomic Energy Agency. Submission or retention of the information is mandatory for persons subject to the requirements.

Dated: February 13, 2024.

For the Nuclear Regulatory Commission.

David C. Cullison,
NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–03237 Filed 2–15–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0215]

Interim Staff Guidance: Material Compatibility for Non-Light Water Reactors; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on February 6, 2024, regarding Interim Staff Guidance (ISG) DANU–ISG–2023–01 “Material Compatibility for non-Light Water Reactors.” This action is necessary to correct the NRC Docket ID.

DATES: The correction takes effect on February 16, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0215 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2022–0215. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Meg Audrain, telephone: 301–415–2133; email: Margaret.Audrain@nrc.gov and Jordan Hoellman, telephone: 301–415–5481; email: Jordan.Hoellman2@nrc.gov. Both are staff of the Office of Nuclear Reactor Regulation at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: Correct "NRC–2022–2015" to read "NRC–2022–0215" in the FR published on February 6, 2024, in FR Doc. 2024–02286, page 8065, within the notice document heading; in the second column,

ADDRESSES section, first sentence; and within the Federal Rulemaking website bullet, first sentence.

Dated: February 12, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

*Chief, Advanced Reactor Policy Branch,
Division of Advanced Reactors and Non-
Power Production and Utilization Facilities,
Office of Nuclear Reactor Regulation.*

[FR Doc. 2024–03203 Filed 2–15–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

**[Docket Nos. MC2024–189 and CP2024–195;
MC2024–190 and CP2024–196]**

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 21, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the

proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s):* MC2024–189 and CP2024–195; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 188 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* February 12, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* February 21, 2024.

2. *Docket No(s):* MC2024–190 and CP2024–196; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 189 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* February 12, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* February 21, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2024–03308 Filed 2–15–24; 8:45 am]

BILLING CODE 7710–FW–P

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–135, OMB Control No. 3235–0176]

Submission for OMB Review; Comment Request; Extension: Rules 8b–1 to 8b–5; 8b–10 to 8b–22; and 8b–25 to 8b–31

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the “Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for extension of the previously approved collection of information discussed below.

Rules 8b–1 to 8b–5; 8b–10 to 8b–22; and 8b–25 to 8b–31 (“rules under Section 8(b)”) (17 CFR 270.8b–1 to 8b–31) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (“Investment Company Act”) set forth the procedures for preparing and filing a registration statement under the Investment Company Act. These procedures are intended to facilitate the registration process. These rules generally do not require respondents to report information.¹

The Commission believes that it is appropriate to estimate the total respondent burden associated with preparing each registration statement form rather than attempt to isolate the impact of the procedural instructions under Section 8(b) of the Investment Company Act, which impose burdens only in the context of the preparation of the various registration statement forms. Accordingly, the Commission is not submitting a separate burden estimate for the rules under Section 8(b), but instead will include the burden for these rules in its estimates of burden for each of the registration forms under the Investment Company Act. The

Commission is, however, submitting an hourly burden estimate of one hour for administrative purposes.

The collection of information under the rules under Section 8(b) is mandatory. The information provided under the rules under Section 8(b) is not kept confidential. 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 public may view background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by March 18, 2024 to (i) MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: February 13, 2024.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024–03271 Filed 2–15–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–86, OMB Control No. 3235–0080]

Proposed Collection; Comment Request; Extension: Rule 12d2–2 and Form 25

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (“PRA”) (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the collections of information provided for in Rule 12d2–2 (17 CFR 240.12d2–2) and Form 25 (17 CFR 249.25) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit these existing collections of information to the Office of Management and Budget (“OMB”) for extension and approval.

On February 12, 1935, the Commission adopted Rule 12d2–2¹ and Form 25, under the Securities Exchange Act of 1934 (“Act”), to establish the conditions and procedures under which a security may be delisted from an exchange and withdrawn from registration under Section 12(b) of the Act.² The Commission adopted amendments to Rule 12d2–2 and Form 25 in 2005.³ Under the amended Rule 12d2–2, all issuers and national securities exchanges seeking to delist and deregister a security in accordance with the rules of an exchange must file the adopted version of Form 25 with the Commission. The Commission also adopted amendments to Rule 19d–1 under the Act to require exchanges to file the adopted version of Form 25 as notice to the Commission under section 19(d) of the Act. Finally, the Commission adopted amendments to exempt standardized options and security futures products from section 12(d) of the Act. These amendments were intended to simplify the paperwork and procedure associated with a delisting and to unify general rules and procedures relating to the delisting process.

Form 25 is useful because it informs the Commission and members of the public that a security previously traded on an exchange is no longer traded. In addition, Form 25 enables the Commission to verify that the delisting and/or deregistration has occurred in accordance with the rules of the exchange. Further, Form 25 helps to focus the attention of delisting issuers to make sure that they abide by the proper procedural and notice requirements associated with a delisting and/or a deregistration. Without Rule 12d2–2 and Form 25, as applicable, the Commission would be unable to fulfill its statutory responsibilities.

There are 24 national securities exchanges that could possibly be respondents complying with the requirements of Rule 12d2–2 and Form 25.⁴ The burden of complying with Rule

¹ See Securities Exchange Act Release No. 98 (Feb. 12, 1935).

² See Securities Exchange Act Release No. 7011 (Feb. 5, 1963), 28 FR 1506 (Feb. 16, 1963).

³ See Securities Exchange Act Release No. 52029 (Jul. 14, 2005), 70 FR 42456 (Jul. 22, 2005).

⁴ The staff notes that a few of these 24 registered national securities exchanges only have rules to permit the listing of standardized options, which are exempt from Rule 12d2–2 under the Act. Nevertheless, the staff counted national securities exchanges that can only list options as potential respondents because these exchanges could potentially adopt new rules, subject to Commission approval under Section 19(b) of the Act, to list and trade equity and other securities that have to comply with Rule 12d2–2 under the Act. Notice

¹ Although the rules under Section 8(b) of the Investment Company Act are generally procedural in nature, two of the rules require respondents to disclose some limited information. Rule 8b–3 (17 CFR 270.8b–3) provides that whenever a registration form requires the title of securities to be stated, the registrant must indicate the type and general character of the securities to be issued. Rule 8b–22 (17 CFR 270.8b–22) provides that if the existence of control is open to reasonable doubt, the registrant may disclaim the existence of control, but it must state the material facts pertinent to the possible existence of control. The information required by both of these rules is necessary to ensure that investors have clear and complete information upon which to base an investment decision.

12d2-2 and Form 25 is not evenly distributed among the exchanges, however, since there are many more securities listed on the New York Stock Exchange, the NASDAQ Stock Market, and NYSE American than on the other exchanges. However, for purposes of this filing, the Commission staff has assumed that the number of responses is evenly divided among the exchanges. Since approximately 985 responses under Rule 12d2-2 and Form 25 for the purpose of delisting and/or deregistration of equity securities are received annually by the Commission from the national securities exchanges, the resultant aggregate annual reporting hour burden would be, assuming on average one hour per response, 985 annual burden hours for all exchanges (24 exchanges × an average of 41.04 responses per exchange × 1 hour per response). In addition, since approximately 117 responses are received by the Commission annually from issuers wishing to remove their securities from listing and registration on exchanges, the Commission staff estimates that the aggregate annual reporting hour burden on issuers would be, assuming on average one reporting hour per response, 117 annual burden hours for all issuers (117 issuers × 1 response per issuer × 1 hour per response). Accordingly, the total annual hour burden for all respondents to comply with Rule 12d2-2 is 1,102 hours (985 hours for exchanges + 117 hours for issuers). The total related internal compliance cost associated with these burden hours is \$269,852 (\$226,796 for exchanges plus \$43,056 for issuers).

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information 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 by April 16, 2024.

registrants that are registered as national securities exchanges solely for the purposes of trading securities futures products have not been counted since, as noted above, securities futures products are exempt from complying with Rule 12d2-2 under the Act and therefore do not have to file Form 25.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: PRA_Mailbox@sec.gov.

Dated: February 13, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-03272 Filed 2-15-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-99521; File No. SR-NYSEAMER-2024-07]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the Connectivity Fee Schedule

February 12, 2024.

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 January 29, 2024, 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 Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey and Canada. 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.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and the 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 the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey ("MDC") ⁴ and Canada. ⁵

The Exchange expects that the proposed rule change would become operative no later than March 31, 2024. The Exchange will announce the date that the proposed services will be available through a customer notice.

Proposed Changes to the Wireless Connections

The Exchange currently offers wireless connections between the MDC and the access center in the Markham, Canada data center ("Markham") of 1, 5 and 10 Mb (the "Markham Connections"). ⁶ The Exchange understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and a data center

⁴ Through its Fixed Income and Data Services ("FIDS") business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and its affiliates the New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (the "Affiliate SROs") are indirect subsidiaries of ICE. Each of the Exchange's Affiliate SROs has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-05, SR-NYSEArca-2024-11, SR-NYSECHX-2024-03, and SR-NYSENat-2024-02.

⁵ Although it presently has proprietary use of it, FIDS does not own the wireless network that would be used to provide the services. The services would be provided by FIDS pursuant to an agreement with one or more non-ICE entities.

⁶ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR-NYSE-2020-05, SR-NYSEAMER-2020-05, SR-NYSEArca-2020-08, SR-NYSECHX-2020-02, SR-NYSENat-2020-03, SR-NYSE-2020-11, SR-NYSEAMER-2020-10, SR-NYSEArca-2020-15, SR-NYSECHX-2020-05, SR-NYSENat-2020-08).

in Toronto, Canada that hosts several Canadian exchanges, including Nasdaq Canada ("TR2"). With such a wireless connection, purchasers' wireless connections to the Toronto area would not be limited to Markham and the exchanges located there. However, the Exchange is not aware of any wireless connection between the MDC and TR2 that is currently commercially available.

To that end, the Exchange proposes to expand its existing wireless bandwidth connections to Markham to include connections of the same size to TR2 (the "TR2 Connections"). As a result of the proposed expansion, a purchaser's wireless bandwidth connection would be between the MDC and both Markham and TR2.⁷

The Exchange proposes to offer this expanded service at no additional charge. The previously filed⁸ initial charge and monthly recurring charge ("MRC") for the Markham Connections would now also include the TR2

Connections as well. Customers purchasing the service would not be required to connect to both Markham and TR2, but if they chose to do so, they could connect to both data centers for the same fees that currently apply to connectivity to Markham only. Customers that currently have a Markham Connection would not have to pay a second initial charge or a second MRC in order to expand their Markham Connection to include a TR2 Connection of the same size.⁹

Under the proposed expanded service, northbound and southbound wireless services would operate in a distinct manner. Data sent northbound from the MDC would be transported to both Canadian access centers such that the same data would be delivered to both Markham and TR2. The customer would not have two independent connections but rather would use a single connection to reach both

Canadian access centers. At each, the customer would have access to the total Mb of the wireless circuit.¹⁰

Southbound, the purchaser could choose to send data from one or both of the Canadian access centers. The purchaser could send data up to the total number of Mb of the wireless circuit from either access center, so long as the combined amount of data that reached the MDC did not exceed the total Mb of the wireless circuit that the customer purchased. The distribution would not be static: the number of Mb of data from either Canadian access center could vary at the customer's discretion.¹¹

In order to implement the proposed change, the Exchange proposes to amend the table under "B. Wireless Connectivity" in the Connectivity Fee Schedule as follows (proposed new text italicized and proposed deletions in brackets):

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	1 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$6,000.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	5 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$15,500.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	10 Mb Circuit ..	\$10,000 per connection initial charge plus monthly charge per connection of \$23,000.

The Exchange also proposes to add the following to the Connectivity Fee Schedule, following the table under "B. Wireless Connectivity" (all text is new):

Wireless Connectivity Note

A customer may purchase a Wireless Connection between the Mahwah Data Center and one or both of (a) the Markham access center and (b) the TR2 access center. If the customer chooses to connect to both Canadian access centers, the northbound and southbound wireless services operate in a distinct manner. Northbound, the same data is sent to both the Markham and TR2 access centers. Southbound, the customer may choose the Mb of data it sends from each Canadian access center, so long as the combined total Mb entering the Mahwah Data Center equals no more than the total Mb of the wireless circuit.

Once a customer requested connectivity to TR2 as part of the

expanded service, FIDS would establish a wireless connection between TR2 and the MDC using the wireless network owned by another party. As is currently true of the Markham Connections, the proposed expanded wireless connection would terminate on a pole off the grounds of the MDC property.¹² Also as currently true of the Markham Connections, the expanded service would not connect directly to the Exchange trading and execution systems.

The Exchange proposes to expand its existing service because it understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and TR2. With such a wireless connection, purchasers' wireless connections would not be limited to

Markham and the exchanges located there.

Customers would have control over what data they send over their TR2 Connection or Markham Connection. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from securities information providers; send risk management, billing, or compliance information; or to carry any other market information or other data they wish to and from their equipment in TR2, Markham, and the MDC. The Exchange would not, and could not, know what data customers sent over the connections and would not send or receive any data over the connections.

⁷ A purchaser would not be required to receive the connection in both Markham and TR2 if they chose to be present in only one Canadian access center.

⁸ See *id.*

⁹ As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived. As is true now, if a customer that had a wireless connection

purchased a larger or smaller size wireless connection to replace it, the customer would not be subject to a second initial charge.

¹⁰ For example, if a customer had a 5 Mb circuit, it would have a 5 Mb connection to Markham and a 5 Mb connection to TR2. A customer that chose to be at both access centers would receive all data that has been sent northbound at both access centers.

¹¹ For example, if a customer had a 5 Mb circuit, southbound the customer could choose to send 3 Mb of data from Markham and 2 Mb of data from TR2 at one moment, and then 1 Mb of data from Markham and 4 Mb of data from TR2 at the next moment.

¹² See 85 FR 67044, note 6, *supra*, at 67054.

General

The proposed changes would apply to all customers equally. The proposed changes would not apply differently to distinct types or sizes of market participants. As is currently the case, the purchase of any connectivity service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all customers.

FIDS has proposed to expand the existing service to include the TR2 Connections at the request of FIDS customers. It does not expect that the proposed change will result in new customers in Markham.

The proposed changes are not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that customers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, because 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 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁵ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed expansion of the existing services is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, because it would increase the connectivity currently

offered by allowing customers to connect to TR2 as well as Markham for no additional charge. Adding this additional connection option would allow the customer to use a wireless bandwidth connection to relay market data and send trading orders between the MDC and the exchanges and alternative trading systems located in TR2. The purchaser would be able to determine what data to transport between the MDC and the two Canadian access centers based on what would best serve its needs, tailoring the service to the requirements of its business operations, at no additional cost to customers.

The Exchange further believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to expand the connectivity options because it would be responsive to requests from customers, who have asked for the TR2 Connections.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

Because the proposed expanded service is designed to offer market participants a means to minimize the latency of their communications, including trading orders, and receipt of market data, it will thereby enhance the efficiency of their trading strategies on the Exchange and elsewhere, and because there is no impediment to competitors offering similar services, the Exchange believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange also believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors

and the public interest because the expanded service including TR2 Connections would be available at the currently filed initial charge and MRC for the Markham Connections, with no additional charge for the expanded service. Accordingly, the Exchange believes that the proposed change is reasonable because the change would mean that a customer would receive an enhanced offering with the option of adding connectivity to a second Canadian access center for the same price that the Exchange currently charges for a connection to one Canadian access center. Customers that currently have a Markham Connection would not have to pay a second initial charge in order to obtain an expanded connection. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

The Exchange believes that it is reasonable that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is reasonable to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is reasonable to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ 15 U.S.C. 78f(b)(4).

transparency of the Connectivity Fee Schedule.

The Proposed Change Is Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed change provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers because the change would mean that a customer would receive an expanded service, with the option of adding connectivity to two Canadian access centers for the same price that the Exchange currently charges for a connection to one Canadian access center.

Customers that currently have a Markham Connection would not have to pay a second initial charge in order to also obtain a TR2 Connection of the same size. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory since, as is true now, only customers that purchased the proposed service would be charged for it. The proposed change would not apply differently to distinct types or sizes of market participants but would apply to all customers equally. Moreover, although the Exchange proposes to expand the connectivity options, a customer that currently has a Markham Connection would not be obligated to make any changes. As is currently the case, the purchase of any connectivity service would be completely voluntary.

The Exchange believes that it is equitable and not unfairly discriminatory that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is equitable and not unfairly discriminatory to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is equitable and not unfairly discriminatory to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one

customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together, and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be equitable and not unfairly discriminatory because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule, making it easier to read and understand and alleviating possible customer confusion for all market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act¹⁶ because it is not designed to address any competitive issues. The proposed rule

change would provide customers with a wider range of choices for wireless connectivity to Canada.

The Exchange believes the wireless connections between MDC and TR2 are the first commercially available wireless connections between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would not impose any burden on competition that is not necessary or appropriate because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange. Indeed, a third party has announced that it plans to create a wireless connection between Markham and the MDC and the Exchange believes it intends to expand its offering to connect to the TR2, underscoring that the Exchange could not impose any impediments to a third party providing wireless connectivity.

The proposed rule change would provide customers the ability to connect to a second Canadian data center for the same price they currently pay to connect to one. All customers would be able to choose if they want connections to one or both Canadian data centers and the size of connection they want. The Exchange does not believe that the proposed rule change would place any customer at a relative disadvantage compared to other customers.

For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁶ 15 U.S.C. 78f(b)(8).

competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and Rule 19b-4(f)(6)(iii) thereunder.²⁰

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)²¹ of the Act 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEAMER-2024-07 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-2024-07. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2024-07 and should be submitted on or before March 8, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-03224 Filed 2-15-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-99523; File No. SR-NYSEARCA-2024-11]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

February 12, 2024.

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 January 29, 2024, NYSE Arca, Inc. ("NYSE Arca" 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 Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey and Canada. 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 the 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 the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey ("MDC")⁴ and Canada.⁵

The Exchange expects that the proposed rule change would become operative no later than March 31, 2024. The Exchange will announce the date that the proposed services will be available through a customer notice.

Proposed Changes to the Wireless Connections

The Exchange currently offers wireless connections between the MDC

⁴ Through its Fixed Income and Data Services ("FIDS") business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and its affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. (the "Affiliate SROs") are indirect subsidiaries of ICE. Each of the Exchange's Affiliate SROs has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-05, SR-NYSEAMER-2024-07, SR-NYSECHX-2024-03, and SR-NYSENAT-2024-02.

⁵ Although it presently has proprietary use of it, FIDS does not own the wireless network that would be used to provide the services. The services would be provided by FIDS pursuant to an agreement with one or more non-ICE entities.

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) 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.

²¹ 15 U.S.C. 78s(b)(2)(B).

²² 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.

and the access center in the Markham, Canada data center (“Markham”) of 1, 5 and 10 Mb (the “Markham Connections”).⁶ The Exchange understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and a data center in Toronto, Canada that hosts several Canadian exchanges, including Nasdaq Canada (“TR2”). With such a wireless connection, purchasers’ wireless connections to the Toronto area would not be limited to Markham and the exchanges located there. However, the Exchange is not aware of any wireless connection between the MDC and TR2 that is currently commercially available.

To that end, the Exchange proposes to expand its existing wireless bandwidth connections to Markham to include connections of the same size to TR2 (the “TR2 Connections”). As a result of the proposed expansion, a purchaser’s wireless bandwidth connection would be between the MDC and both Markham and TR2.⁷

The Exchange proposes to offer this expanded service at no additional charge. The previously filed⁸ initial charge and monthly recurring charge (“MRC”) for the Markham Connections would now also include the TR2 Connections as well. Customers purchasing the service would not be required to connect to both Markham and TR2, but if they chose to do so, they could connect to both data centers for the same fees that currently apply to connectivity to Markham only. Customers that currently have a Markham Connection would not have to pay a second initial charge or a second MRC in order to expand their Markham Connection to include a TR2 Connection of the same size.⁹

Under the proposed expanded service, northbound and southbound wireless services would operate in a distinct manner. Data sent northbound from the MDC would be transported to both Canadian access centers such that the same data would be delivered to both Markham and TR2. The customer would not have two independent

connections but rather would use a single connection to reach both Canadian access centers. At each, the customer would have access to the total Mb of the wireless circuit.¹⁰

Southbound, the purchaser could choose to send data from one or both of the Canadian access centers. The purchaser could send data up to the total number of Mb of the wireless circuit from either access center, so long as the combined amount of data that reached the MDC did not exceed the total Mb of the wireless circuit that the customer purchased. The distribution would not be static: the number of Mb of data from either Canadian access center could vary at the customer’s discretion.¹¹

In order to implement the proposed change, the Exchange proposes to amend the table under “B. Wireless Connectivity” in the Connectivity Fee Schedule as follows (proposed new text italicized and proposed deletions in brackets):

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	1 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$6,000.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	5 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$15,500.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	10 Mb Circuit ..	\$10,000 per connection initial charge plus monthly charge per connection of \$23,000.

The Exchange also proposes to add the following to the Connectivity Fee Schedule, following the table under “B. Wireless Connectivity” (all text is new):

Wireless Connectivity Note

A customer may purchase a Wireless Connection between the Mahwah Data Center and one or both of (a) the Markham access center and (b) the TR2 access center. If the customer chooses to connect to both Canadian access centers, the northbound and southbound wireless services operate in a distinct manner. Northbound, the same data is sent to both the Markham and TR2 access centers. Southbound, the customer may choose the Mb of data it sends from each Canadian access center, so long as the

combined total Mb entering the Mahwah Data Center equals no more than the total Mb of the wireless circuit.

Once a customer requested connectivity to TR2 as part of the expanded service, FIDS would establish a wireless connection between TR2 and the MDC using the wireless network owned by another party. As is currently true of the Markham Connections, the proposed expanded wireless connection would terminate on a pole off the grounds of the MDC property.¹² Also as currently true of the Markham Connections, the expanded service would not connect directly to the

Exchange trading and execution systems.

The Exchange proposes to expand its existing service because it understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and TR2. With such a wireless connection, purchasers’ wireless connections would not be limited to Markham and the exchanges located there.

Customers would have control over what data they send over their TR2 Connection or Markham Connection. They may, but are not required to, use

to be at both access centers would receive all data that has been sent northbound at both access centers.

¹¹ For example, if a customer had a 5 Mb circuit, southbound the customer could choose to send 3 Mb of data from Markham and 2 Mb of data from TR2 at one moment, and then 1 Mb of data from Markham and 4 Mb of data from TR2 at the next moment.

¹² See 85 FR 67044, note 6, *supra*, at 67054.

⁶ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR-NYSE-2020-05, SR-NYSEAMER-2020-05, SR-NYSEArca-2020-08, SR-NYSECHX-2020-02, SR-NYSENAT-2020-03, SR-NYSE-2020-11, SR-NYSEAMER-2020-10, SR-NYSEArca-2020-15, SR-NYSECHX-2020-05, SR-NYSENAT-2020-08).

⁷ A purchaser would not be required to receive the connection in both Markham and TR2 if they chose to be present in only one Canadian access center.

⁸ See *id.*

⁹ As is currently true for Markham Connections, a customer that purchased a new connection would have its first month’s MRC waived. As is true now, if a customer that had a wireless connection purchased a larger or smaller size wireless connection to replace it, the customer would not be subject to a second initial charge.

¹⁰ For example, if a customer had a 5 Mb circuit, it would have a 5 Mb connection to Markham and a 5 Mb connection to TR2. A customer that chose

them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from securities information processors; send risk management, billing, or compliance information; or to carry any other market information or other data they wish to and from their equipment in TR2, Markham, and the MDC. The Exchange would not, and could not, know what data customers sent over the connections and would not send or receive any data over the connections.

General

The proposed changes would apply to all customers equally. The proposed changes would not apply differently to distinct types or sizes of market participants. As is currently the case, the purchase of any connectivity service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all customers.

FIDS has proposed to expand the existing service to include the TR2 Connections at the request of FIDS customers. It does not expect that the proposed change will result in new customers in Markham.

The proposed changes are not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that customers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, because 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 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁵ because it provides for the equitable allocation of

reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change is Reasonable

The Exchange believes that the proposed expansion of the existing services is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, because it would increase the connectivity currently offered by allowing customers to connect to TR2 as well as Markham for no additional charge. Adding this additional connection option would allow the customer to use a wireless bandwidth connection to relay market data and send trading orders between the MDC and the exchanges and alternative trading systems located in TR2. The purchaser would be able to determine what data to transport between the MDC and the two Canadian access centers based on what would best serve its needs, tailoring the service to the requirements of its business operations, at no additional cost to customers.

The Exchange further believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to expand the connectivity options because it would be responsive to requests from customers, who have asked for the TR2 Connections.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

Because the proposed expanded service is designed to offer market participants a means to minimize the latency of their communications, including trading orders, and receipt of market data, it will thereby enhance the

efficiency of their trading strategies on the Exchange and elsewhere, and because there is no impediment to competitors offering similar services, the Exchange believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange also believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because the expanded service including TR2 Connections would be available at the currently filed initial charge and MRC for the Markham Connections, with no additional charge for the expanded service. Accordingly, the Exchange believes that the proposed change is reasonable because the change would mean that a customer would receive an enhanced offering with the option of adding connectivity to a second Canadian access center for the same price that the Exchange currently charges for a connection to one Canadian access center. Customers that currently have a Markham Connection would not have to pay a second initial charge in order to obtain an expanded connection. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

The Exchange believes that it is reasonable that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is reasonable to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is reasonable to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ 15 U.S.C. 78f(b)(4).

Canadian access centers, that matters to the Exchange.

The Exchange believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule.

The Proposed Change Is Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed change provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers because the change would mean that a customer would receive an expanded service, with the option of adding connectivity to two Canadian access centers for the same price that the Exchange currently charges for a connection to one Canadian access center.

Customers that currently have a Markham Connection would not have to pay a second initial charge in order to also obtain a TR2 Connection of the same size. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory since, as is true now, only customers that purchased the proposed service would be charged for it. The proposed change would not apply differently to distinct types or sizes of market participants but would apply to all customers equally. Moreover, although the Exchange proposes to expand the connectivity options, a customer that currently has a Markham Connection would not be obligated to make any changes. As is currently the case, the purchase of any connectivity service would be completely voluntary.

The Exchange believes that it is equitable and not unfairly discriminatory that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is

equitable and not unfairly discriminatory to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is equitable and not unfairly discriminatory to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together, and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be equitable and not unfairly discriminatory because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule, making it easier to read and understand and alleviating possible customer confusion for all market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act¹⁶ because it is not designed to address any competitive issues. The proposed rule change would provide customers with a wider range of choices for wireless connectivity to Canada.

The Exchange believes the wireless connections between MDC and TR2 are the first commercially available wireless connections between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would not impose any burden on competition that is not necessary or appropriate because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange. Indeed, a third party has announced that it plans to create a wireless connection between Markham and the MDC and the Exchange believes it intends to expand its offering to connect to the TR2, underscoring that the Exchange could not impose any impediments to a third party providing wireless connectivity.

The proposed rule change would provide customers the ability to connect to a second Canadian data center for the same price they currently pay to connect to one. All customers would be able to choose if they want connections to one or both Canadian data centers and the size of connection they want. The Exchange does not believe that the proposed rule change would place any customer at a relative disadvantage compared to other customers.

For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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.

¹⁶ 15 U.S.C. 78f(b)(8).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸ Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and Rule 19b-4(f)(6)(iii) thereunder.²⁰

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)²¹ of the Act 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2024-11 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-2024-11. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2024-11 and should be submitted on or before March 8, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-03226 Filed 2-15-24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-99519; File No. SR-NYSEARCA-2024-02]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

February 12, 2024

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 January 29, 2024, NYSE National, Inc. ("NYSE National" 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 Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey and Canada. 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 the 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 the Connectivity Fee Schedule to expand

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) 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.

²¹ 15 U.S.C. 78s(b)(2)(B).

²² 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.

existing wireless connections between the data center in Mahwah, New Jersey (“MDC”)⁴ and Canada.⁵

The Exchange expects that the proposed rule change would become operative no later than March 31, 2024. The Exchange will announce the date that the proposed services will be available through a customer notice.

Proposed Changes to the Wireless Connections

The Exchange currently offers wireless connections between the MDC and the access center in the Markham, Canada data center (“Markham”) of 1, 5 and 10 Mb (the “Markham Connections”).⁶ The Exchange understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and a data center in Toronto, Canada that hosts several Canadian exchanges, including Nasdaq Canada (“TR2”). With such a wireless connection, purchasers’ wireless connections to the Toronto area would not be limited to Markham and the exchanges located there. However, the Exchange is not aware of any wireless

connection between the MDC and TR2 that is currently commercially available.

To that end, the Exchange proposes to expand its existing wireless bandwidth connections to Markham to include connections of the same size to TR2 (the “TR2 Connections”). As a result of the proposed expansion, a purchaser’s wireless bandwidth connection would be between the MDC and both Markham and TR2.⁷

The Exchange proposes to offer this expanded service at no additional charge. The previously filed⁸ initial charge and monthly recurring charge (“MRC”) for the Markham Connections would now also include the TR2 Connections as well. Customers purchasing the service would not be required to connect to both Markham and TR2, but if they chose to do so, they could connect to both data centers for the same fees that currently apply to connectivity to Markham only. Customers that currently have a Markham Connection would not have to pay a second initial charge or a second MRC in order to expand their Markham Connection to include a TR2 Connection of the same size.⁹

Under the proposed expanded service, northbound and southbound wireless services would operate in a

distinct manner. Data sent northbound from the MDC would be transported to both Canadian access centers such that the same data would be delivered to both Markham and TR2. The customer would not have two independent connections but rather would use a single connection to reach both Canadian access centers. At each, the customer would have access to the total Mb of the wireless circuit.¹⁰

Southbound, the purchaser could choose to send data from one or both of the Canadian access centers. The purchaser could send data up to the total number of Mb of the wireless circuit from either access center, so long as the combined amount of data that reached the MDC did not exceed the total Mb of the wireless circuit that the customer purchased. The distribution would not be static: the number of Mb of data from either Canadian access center could vary at the customer’s discretion.¹¹

In order to implement the proposed change, the Exchange proposes to amend the table under “B. Wireless Connectivity” in the Connectivity Fee Schedule as follows (proposed new text italicized and proposed deletions in brackets):

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	1 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$6,000.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	5 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$15,500.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	10 Mb Circuit ..	\$10,000 per connection initial charge plus monthly charge per connection of \$23,000.

The Exchange also proposes to add the following to the Connectivity Fee Schedule, following the table under “B. Wireless Connectivity” (all text is new):

Wireless Connectivity Note

A customer may purchase a Wireless Connection between the Mahwah Data Center

and one or both of (a) the Markham access center and (b) the TR2 access center. If the customer chooses to connect to both Canadian access centers, the northbound and southbound wireless services operate in a distinct manner. Northbound, the same data is sent to both the Markham and TR2 access centers. Southbound, the customer may choose the Mb of data it sends from each

Canadian access center, so long as the combined total Mb entering the Mahwah Data Center equals no more than the total Mb of the wireless circuit.

Once a customer requested connectivity to TR2 as part of the expanded service, FIDS would establish a wireless connection between TR2 and

⁴ Through its Fixed Income and Data Services (“FIDS”) business, Intercontinental Exchange, Inc. (“ICE”) operates the MDC. The Exchange and its affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc. (the “Affiliate SROs”) are indirect subsidiaries of ICE. Each of the Exchange’s Affiliate SROs has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-05, SR-NYSEAMER-2024-07, SR-NYSEArca-2024-11, and SR-NYSECHX-2024-03.

⁵ Although it presently has proprietary use of it, FIDS does not own the wireless network that would be used to provide the services. The services would be provided by FIDS pursuant to an agreement with one or more non-ICE entities.

⁶ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR-NYSE-2020-05, SR-NYSEAMER-2020-05, SR-NYSEArca-2020-08, SR-NYSECHX-2020-02, SR-NYSENAT-2020-03, SR-NYSE-2020-11, SR-NYSEAMER-2020-10, SR-NYSEArca-2020-15, SR-NYSECHX-2020-05, SR-NYSENAT-2020-08).

⁷ A purchaser would not be required to receive the connection in both Markham and TR2 if they chose to be present in only one Canadian access center.

⁸ See *id.*

⁹ As is currently true for Markham Connections, a customer that purchased a new connection would have its first month’s MRC waived. As is true now, if a customer that had a wireless connection

purchased a larger or smaller size wireless connection to replace it, the customer would not be subject to a second initial charge.

¹⁰ For example, if a customer had a 5 Mb circuit, it would have a 5 Mb connection to Markham and a 5 Mb connection to TR2. A customer that chose to be at both access centers would receive all data that has been sent northbound at both access centers.

¹¹ For example, if a customer had a 5 Mb circuit, southbound the customer could choose to send 3 Mb of data from Markham and 2 Mb of data from TR2 at one moment, and then 1 Mb of data from Markham and 4 Mb of data from TR2 at the next moment.

the MDC using the wireless network owned by another party. As is currently true of the Markham Connections, the proposed expanded wireless connection would terminate on a pole off the grounds of the MDC property.¹² Also as currently true of the Markham Connections, the expanded service would not connect directly to the Exchange trading and execution systems.

The Exchange proposes to expand its existing service because it understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and TR2. With such a wireless connection, purchasers' wireless connections would not be limited to Markham and the exchanges located there.

Customers would have control over what data they send over their TR2 Connection or Markham Connection. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from securities information processors; send risk management, billing, or compliance information; or to carry any other market information or other data they wish to and from their equipment in TR2, Markham, and the MDC. The Exchange would not, and could not, know what data customers sent over the connections and would not send or receive any data over the connections.

General

The proposed changes would apply to all customers equally. The proposed changes would not apply differently to distinct types or sizes of market participants. As is currently the case, the purchase of any connectivity service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all customers.

FIDS has proposed to expand the existing service to include the TR2 Connections at the request of FIDS customers. It does not expect that the proposed change will result in new customers in Markham.

The proposed changes are not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that customers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, because 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 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁵ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed expansion of the existing services is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, because it would increase the connectivity currently offered by allowing customers to connect to TR2 as well as Markham for no additional charge. Adding this additional connection option would allow the customer to use a wireless bandwidth connection to relay market data and send trading orders between the MDC and the exchanges and alternative trading systems located in TR2. The purchaser would be able to determine what data to transport between the MDC and the two Canadian access centers based on what would best serve its needs, tailoring the service to the requirements of its business operations, at no additional cost to customers.

The Exchange further believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to expand the connectivity options because it would be responsive

to requests from customers, who have asked for the TR2 Connections.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

Because the proposed expanded service is designed to offer market participants a means to minimize the latency of their communications, including trading orders, and receipt of market data, it will thereby enhance the efficiency of their trading strategies on the Exchange and elsewhere, and because there is no impediment to competitors offering similar services, the Exchange believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange also believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because the expanded service including TR2 Connections would be available at the currently filed initial charge and MRC for the Markham Connections, with no additional charge for the expanded service. Accordingly, the Exchange believes that the proposed change is reasonable because the change would mean that a customer would receive an enhanced offering with the option of adding connectivity to a second Canadian access center for the same price that the Exchange currently charges for a connection to one Canadian access center. Customers that currently have a Markham Connection would not have to pay a second initial charge in order to obtain an expanded connection. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ 15 U.S.C. 78f(b)(4).

¹² See 85 FR 67044, note 6, *supra*, at 67054.

The Exchange believes that it is reasonable that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is reasonable to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is reasonable to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule.

The Proposed Change Is Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed change provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers because the change would mean that a customer would receive an expanded service, with the option of adding connectivity to two Canadian access centers for the same price that the Exchange currently charges for a connection to one Canadian access center.

Customers that currently have a Markham Connection would not have to pay a second initial charge in order to

also obtain a TR2 Connection of the same size. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory since, as is true now, only customers that purchased the proposed service would be charged for it. The proposed change would not apply differently to distinct types or sizes of market participants but would apply to all customers equally. Moreover, although the Exchange proposes to expand the connectivity options, a customer that currently has a Markham Connection would not be obligated to make any changes. As is currently the case, the purchase of any connectivity service would be completely voluntary.

The Exchange believes that it is equitable and not unfairly discriminatory that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is equitable and not unfairly discriminatory to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is equitable and not unfairly discriminatory to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together, and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be equitable and not unfairly discriminatory because market participants may create their own

proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule, making it easier to read and understand and alleviating possible customer confusion for all market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act¹⁶ because it is not designed to address any competitive issues. The proposed rule change would provide customers with a wider range of choices for wireless connectivity to Canada.

The Exchange believes the wireless connections between MDC and TR2 are the first commercially available wireless connections between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would not impose any burden on competition that is not necessary or appropriate because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange. Indeed, a third party has announced that it plans to create a wireless connection between Markham

¹⁶ 15 U.S.C. 78f(b)(8).

and the MDC and the Exchange believes it intends to expand its offering to connect to the TR2, underscoring that the Exchange could not impose any impediments to a third party providing wireless connectivity.

The proposed rule change would provide customers the ability to connect to a second Canadian data center for the same price they currently pay to connect to one. All customers would be able to choose if they want connections to one or both Canadian data centers and the size of connection they want. The Exchange does not believe that the proposed rule change would place any customer at a relative disadvantage compared to other customers.

For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸ Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and Rule 19b-4(f)(6)(iii) thereunder.²⁰

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)²¹ of the Act 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSENAT-2024-02 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-NYSENAT-2024-02. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or

withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSENAT-2024-02 and should be submitted on or before March 8, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,
Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-99522; File No. SR-NYSECHX-2024-03]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend the Connectivity Fee Schedule

February 12, 2024.

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 January 29, 2024, the NYSE Chicago, Inc. ("NYSE Chicago" 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 Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey and Canada. 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 the 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

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) 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.

²¹ 15 U.S.C. 78s(b)(2)(B).

²² 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.

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 the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey ("MDC")⁴ and Canada.⁵

The Exchange expects that the proposed rule change would become operative no later than March 31, 2024. The Exchange will announce the date that the proposed services will be available through a customer notice.

Proposed Changes to the Wireless Connections

The Exchange currently offers wireless connections between the MDC and the access center in the Markham, Canada data center ("Markham") of 1, 5 and 10 Mb (the "Markham Connections").⁶ The Exchange understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and

relay market data between their equipment in the MDC and a data center in Toronto, Canada that hosts several Canadian exchanges, including Nasdaq Canada ("TR2"). With such a wireless connection, purchasers' wireless connections to the Toronto area would not be limited to Markham and the exchanges located there. However, the Exchange is not aware of any wireless connection between the MDC and TR2 that is currently commercially available.

To that end, the Exchange proposes to expand its existing wireless bandwidth connections to Markham to include connections of the same size to TR2 (the "TR2 Connections"). As a result of the proposed expansion, a purchaser's wireless bandwidth connection would be between the MDC and both Markham and TR2.⁷

The Exchange proposes to offer this expanded service at no additional charge. The previously filed⁸ initial charge and monthly recurring charge ("MRC") for the Markham Connections would now also include the TR2 Connections as well. Customers purchasing the service would not be required to connect to both Markham and TR2, but if they chose to do so, they could connect to both data centers for the same fees that currently apply to connectivity to Markham only. Customers that currently have a Markham Connection would not have to pay a second initial charge or a second MRC in order to expand their Markham

Connection to include a TR2 Connection of the same size.⁹

Under the proposed expanded service, northbound and southbound wireless services would operate in a distinct manner. Data sent northbound from the MDC would be transported to both Canadian access centers such that the same data would be delivered to both Markham and TR2. The customer would not have two independent connections but rather would use a single connection to reach both Canadian access centers. At each, the customer would have access to the total Mb of the wireless circuit.¹⁰

Southbound, the purchaser could choose to send data from one or both of the Canadian access centers. The purchaser could send data up to the total number of Mb of the wireless circuit from either access center, so long as the combined amount of data that reached the MDC did not exceed the total Mb of the wireless circuit that the customer purchased. The distribution would not be static: the number of Mb of data from either Canadian access center could vary at the customer's discretion.¹¹

In order to implement the proposed change, the Exchange proposes to amend the table under "B. Wireless Connectivity" in the Connectivity Fee Schedule as follows (proposed new text italicized and proposed deletions in brackets):

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	1 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$6,000.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	5 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$15,500.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	10 Mb Circuit ..	\$10,000 per connection initial charge plus monthly charge per connection of \$23,000.

The Exchange also proposes to add the following to the Connectivity Fee

Schedule, following the table under "B. Wireless Connectivity" (all text is new):

Wireless Connectivity Note

A customer may purchase a Wireless Connection between the Mahwah Data Center

⁴ Through its Fixed Income and Data Services ("FIDS") business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and its affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (the "Affiliate SROs") are indirect subsidiaries of ICE. Each of the Exchange's Affiliate SROs has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSE-2024-05, SR-NYSEAMER-2024-07, SR-NYSEArca-2024-11, and SR-NYSENAT-2024-02.

⁵ Although it presently has proprietary use of it, FIDS does not own the wireless network that would be used to provide the services. The services would be provided by FIDS pursuant to an agreement with one or more non-ICE entities.

⁶ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR-NYSE-2020-05, SR-NYSEAMER-2020-05, SR-NYSEArca-2020-08, SR-NYSECHX-2020-02, SR-NYSENAT-2020-03, SR-NYSE-2020-11, SR-NYSEAMER-2020-10, SR-NYSEArca-2020-15, SR-NYSECHX-2020-05, SR-NYSENAT-2020-08).

⁷ A purchaser would not be required to receive the connection in both Markham and TR2 if they chose to be present in only one Canadian access center.

⁸ See *id.*

⁹ As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived. As is true now, if a customer that had a wireless connection

purchased a larger or smaller size wireless connection to replace it, the customer would not be subject to a second initial charge.

¹⁰ For example, if a customer had a 5 Mb circuit, it would have a 5 Mb connection to Markham and a 5 Mb connection to TR2. A customer that chose to be at both access centers would receive all data that has been sent northbound at both access centers.

¹¹ For example, if a customer had a 5 Mb circuit, southbound the customer could choose to send 3 Mb of data from Markham and 2 Mb of data from TR2 at one moment, and then 1 Mb of data from Markham and 4 Mb of data from TR2 at the next moment.

and one or both of (a) the Markham access center and (b) the TR2 access center. If the customer chooses to connect to both Canadian access centers, the northbound and southbound wireless services operate in a distinct manner. Northbound, the same data is sent to both the Markham and TR2 access centers. Southbound, the customer may choose the Mb of data it sends from each Canadian access center, so long as the combined total Mb entering the Mahwah Data Center equals no more than the total Mb of the wireless circuit.

Once a customer requested connectivity to TR2 as part of the expanded service, FIDS would establish a wireless connection between TR2 and the MDC using the wireless network owned by another party. As is currently true of the Markham Connections, the proposed expanded wireless connection would terminate on a pole off the grounds of the MDC property.¹² Also as currently true of the Markham Connections, the expanded service would not connect directly to the Exchange trading and execution systems.

The Exchange proposes to expand its existing service because it understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and TR2. With such a wireless connection, purchasers' wireless connections would not be limited to Markham and the exchanges located there.

Customers would have control over what data they send over their TR2 Connection or Markham Connection. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from securities information processors; send risk management, billing, or compliance information; or to carry any other market information or other data they wish to and from their equipment in TR2, Markham, and the MDC. The Exchange would not, and could not, know what data customers sent over the connections and would not send or receive any data over the connections.

General

The proposed changes would apply to all customers equally. The proposed changes would not apply differently to distinct types or sizes of market participants. As is currently the case, the purchase of any connectivity service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all customers.

FIDS has proposed to expand the existing service to include the TR2 Connections at the request of FIDS customers. It does not expect that the proposed change will result in new customers in Markham.

The proposed changes are not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that customers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, because 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 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁵ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change is Reasonable

The Exchange believes that the proposed expansion of the existing services is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, because it would increase the connectivity currently offered by allowing customers to connect to TR2 as well as Markham for no additional charge. Adding this additional connection option would allow the customer to use a wireless bandwidth connection to relay market data and send trading orders between the MDC and the exchanges and alternative trading systems located in TR2. The purchaser would be able to

determine what data to transport between the MDC and the two Canadian access centers based on what would best serve its needs, tailoring the service to the requirements of its business operations, at no additional cost to customers.

The Exchange further believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to expand the connectivity options because it would be responsive to requests from customers, who have asked for the TR2 Connections.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

Because the proposed expanded service is designed to offer market participants a means to minimize the latency of their communications, including trading orders, and receipt of market data, it will thereby enhance the efficiency of their trading strategies on the Exchange and elsewhere, and because there is no impediment to competitors offering similar services, the Exchange believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange also believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because the expanded service including TR2 Connections would be available at the currently filed initial charge and MRC for the Markham Connections, with no additional charge for the expanded service. Accordingly, the Exchange believes that the proposed change is reasonable because the change would mean that a customer would receive an

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ 15 U.S.C. 78f(b)(4).

¹² See 85 FR 67044, note 6, *supra*, at 67054.

enhanced offering with the option of adding connectivity to a second Canadian access center for the same price that the Exchange currently charges for a connection to one Canadian access center. Customers that currently have a Markham Connection would not have to pay a second initial charge in order to obtain an expanded connection. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

The Exchange believes that it is reasonable that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is reasonable to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is reasonable to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule.

The Proposed Change Is Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed change provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons

using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers because the change would mean that a customer would receive an expanded service, with the option of adding connectivity to two Canadian access centers for the same price that the Exchange currently charges for a connection to one Canadian access center.

Customers that currently have a Markham Connection would not have to pay a second initial charge in order to also obtain a TR2 Connection of the same size. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory since, as is true now, only customers that purchased the proposed service would be charged for it. The proposed change would not apply differently to distinct types or sizes of market participants but would apply to all customers equally. Moreover, although the Exchange proposes to expand the connectivity options, a customer that currently has a Markham Connection would not be obligated to make any changes. As is currently the case, the purchase of any connectivity service would be completely voluntary.

The Exchange believes that it is equitable and not unfairly discriminatory that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is equitable and not unfairly discriminatory to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is equitable and not unfairly discriminatory to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together, and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of

Canadian access centers, that matters to the Exchange.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be equitable and not unfairly discriminatory because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule, making it easier to read and understand and alleviating possible customer confusion for all market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act¹⁶ because it is not designed to address any competitive issues. The proposed rule change would provide customers with a wider range of choices for wireless connectivity to Canada.

The Exchange believes the wireless connections between MDC and TR2 are the first commercially available wireless connections between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would not

¹⁶ 15 U.S.C. 78f(b)(8).

impose any burden on competition that is not necessary or appropriate because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange. Indeed, a third party has announced that it plans to create a wireless connection between Markham and the MDC and the Exchange believes it intends to expand its offering to connect to the TR2, underscoring that the Exchange could not impose any impediments to a third party providing wireless connectivity.

The proposed rule change would provide customers the ability to connect to a second Canadian data center for the same price they currently pay to connect to one. All customers would be able to choose if they want connections to one or both Canadian data centers and the size of connection they want. The Exchange does not believe that the proposed rule change would place any customer at a relative disadvantage compared to other customers.

For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸ Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)

of the Act¹⁹ and Rule 19b-4(f)(6)(iii) thereunder.²⁰

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)²¹ of the Act 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 (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSECHX-2024-03 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-NYSECHX-2024-03. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSECHX-2024-03 and should be submitted on or before March 8, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-03223 Filed 2-15-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-99520; File No. SR-NYSE-2024-05]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

February 12, 2024.

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 January 29, 2024, New York Stock Exchange LLC ("NYSE" 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 Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) 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.

²¹ 15 U.S.C. 78s(b)(2)(B).

²² 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.

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6).

the data center in Mahwah, New Jersey and Canada. 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 the 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule to expand existing wireless connections between the data center in Mahwah, New Jersey ("MDC")⁴ and Canada.⁵

The Exchange expects that the proposed rule change would become operative no later than March 31, 2024. The Exchange will announce the date that the proposed services will be available through a customer notice.

Proposed Changes to the Wireless Connections

The Exchange currently offers wireless connections between the MDC and the access center in the Markham, Canada data center ("Markham") of 1, 5 and 10 Mb (the "Markham Connections").⁶ The Exchange understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and a data center in Toronto, Canada that hosts several Canadian exchanges, including Nasdaq Canada ("TR2"). With such a wireless connection, purchasers' wireless connections to the Toronto area would not be limited to Markham and the exchanges located there. However, the Exchange is not aware of any wireless connection between the MDC and TR2 that is currently commercially available.

To that end, the Exchange proposes to expand its existing wireless bandwidth connections to Markham to include connections of the same size to TR2 (the "TR2 Connections"). As a result of the proposed expansion, a purchaser's wireless bandwidth connection would be between the MDC and both Markham and TR2.⁷

The Exchange proposes to offer this expanded service at no additional charge. The previously filed⁸ initial charge and monthly recurring charge ("MRC") for the Markham Connections would now also include the TR2 Connections as well. Customers purchasing the service would not be required to connect to both Markham and TR2, but if they chose to do so, they could connect to both data centers for

the same fees that currently apply to connectivity to Markham only. Customers that currently have a Markham Connection would not have to pay a second initial charge or a second MRC in order to expand their Markham Connection to include a TR2 Connection of the same size.⁹

Under the proposed expanded service, northbound and southbound wireless services would operate in a distinct manner. Data sent northbound from the MDC would be transported to both Canadian access centers such that the same data would be delivered to both Markham and TR2. The customer would not have two independent connections but rather would use a single connection to reach both Canadian access centers. At each, the customer would have access to the total Mb of the wireless circuit.¹⁰

Southbound, the purchaser could choose to send data from one or both of the Canadian access centers. The purchaser could send data up to the total number of Mb of the wireless circuit from either access center, so long as the combined amount of data that reached the MDC did not exceed the total Mb of the wireless circuit that the customer purchased. The distribution would not be static: the number of Mb of data from either Canadian access center could vary at the customer's discretion.¹¹

In order to implement the proposed change, the Exchange proposes to amend the table under "B. Wireless Connectivity" in the Connectivity Fee Schedule as follows (proposed new text italicized and proposed deletions in brackets):

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	1 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$6,000.
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	5 Mb Circuit	\$10,000 per connection initial charge plus monthly charge per connection of \$15,500.

⁴ Through its Fixed Income and Data Services ("FIDS") business, Intercontinental Exchange, Inc. ("ICE") operates the MDC. The Exchange and its affiliates NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (the "Affiliate SROs") are indirect subsidiaries of ICE. Each of the Exchange's Affiliate SROs has submitted substantially the same proposed rule change to propose the changes described herein. See SR-NYSEAMER-2024-07, SR-NYSEArca-2024-11, SR-NYSECHX-2024-03, and SR-NYSENAT-2024-02.

⁵ Although it presently has proprietary use of it, FIDS does not own the wireless network that would be used to provide the services. The services would be provided by FIDS pursuant to an agreement with one or more non-ICE entities.

⁶ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044 (October 21, 2020) (SR-NYSE-2020-05, SR-NYSEAMER-2020-05, SR-NYSEArca-2020-08, SR-NYSECHX-2020-02, SR-NYSENAT-2020-03, SR-NYSE-2020-11, SR-NYSEAMER-2020-10, SR-NYSEArca-2020-15, SR-NYSECHX-2020-05, SR-NYSENAT-2020-08).

⁷ A purchaser would not be required to receive the connection in both Markham and TR2 if they chose to be present in only one Canadian access center.

⁸ See *id.*

⁹ As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived. As is true now, if a customer that had a wireless connection

purchased a larger or smaller size wireless connection to replace it, the customer would not be subject to a second initial charge.

¹⁰ For example, if a customer had a 5 Mb circuit, it would have a 5 Mb connection to Markham and a 5 Mb connection to TR2. A customer that chose to be at both access centers would receive all data that has been sent northbound at both access centers.

¹¹ For example, if a customer had a 5 Mb circuit, southbound the customer could choose to send 3 Mb of data from Markham and 2 Mb of data from TR2 at one moment, and then 1 Mb of data from Markham and 4 Mb of data from TR2 at the next moment.

Type of service	Description	Amount of charge
Wireless Connections between Mahwah Data Center and <i>one or both of (a) Markham access center and (b) TR2 access center.</i>	10 Mb Circuit ..	\$10,000 per connection initial charge plus monthly charge per connection of \$23,000.

The Exchange also proposes to add the following to the Connectivity Fee Schedule, following the table under “B. Wireless Connectivity” (all text is new):

Wireless Connectivity Note

A customer may purchase a Wireless Connection between the Mahwah Data Center and one or both of (a) the Markham access center and (b) the TR2 access center. If the customer chooses to connect to both Canadian access centers, the northbound and southbound wireless services operate in a distinct manner. Northbound, the same data is sent to both the Markham and TR2 access centers. Southbound, the customer may choose the Mb of data it sends from each Canadian access center, so long as the combined total Mb entering the Mahwah Data Center equals no more than the total Mb of the wireless circuit.

Once a customer requested connectivity to TR2 as part of the expanded service, FIDS would establish a wireless connection between TR2 and the MDC using the wireless network owned by another party. As is currently true of the Markham Connections, the proposed expanded wireless connection would terminate on a pole off the grounds of the MDC property.¹² Also as currently true of the Markham Connections, the expanded service would not connect directly to the Exchange trading and execution systems.

The Exchange proposes to expand its existing service because it understands that purchasers may also wish to use a wireless bandwidth connection to send trading orders and relay market data between their equipment in the MDC and TR2. With such a wireless connection, purchasers’ wireless connections would not be limited to Markham and the exchanges located there.

Customers would have control over what data they send over their TR2 Connection or Markham Connection. They may, but are not required to, use them to send trading orders to their equipment in co-location; relay Exchange market data, third party market data and public quote feeds from securities information processors; send risk management, billing, or compliance information; or to carry any other market information or other data they wish to and from their equipment in TR2, Markham, and the MDC. The

Exchange would not, and could not, know what data customers sent over the connections and would not send or receive any data over the connections.

General

The proposed changes would apply to all customers equally. The proposed changes would not apply differently to distinct types or sizes of market participants. As is currently the case, the purchase of any connectivity service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all customers.

FIDS has proposed to expand the existing service to include the TR2 Connections at the request of FIDS customers. It does not expect that the proposed change will result in new customers in Markham.

The proposed changes are not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that customers would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁴ in particular, because 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 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁵ because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and

does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed expansion of the existing services is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest, because it would increase the connectivity currently offered by allowing customers to connect to TR2 as well as Markham for no additional charge. Adding this additional connection option would allow the customer to use a wireless bandwidth connection to relay market data and send trading orders between the MDC and the exchanges and alternative trading systems located in TR2. The purchaser would be able to determine what data to transport between the MDC and the two Canadian access centers based on what would best serve its needs, tailoring the service to the requirements of its business operations, at no additional cost to customers.

The Exchange further believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to expand the connectivity options because it would be responsive to requests from customers, who have asked for the TR2 Connections.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

Because the proposed expanded service is designed to offer market

¹² See 85 FR 67044, note 6, *supra*, at 67054.

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

¹⁵ 15 U.S.C. 78f(b)(4).

participants a means to minimize the latency of their communications, including trading orders, and receipt of market data, it will thereby enhance the efficiency of their trading strategies on the Exchange and elsewhere, and because there is no impediment to competitors offering similar services, the Exchange believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange also believes that the proposed change is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because the expanded service including TR2 Connections would be available at the currently filed initial charge and MRC for the Markham Connections, with no additional charge for the expanded service. Accordingly, the Exchange believes that the proposed change is reasonable because the change would mean that a customer would receive an enhanced offering with the option of adding connectivity to a second Canadian access center for the same price that the Exchange currently charges for a connection to one Canadian access center. Customers that currently have a Markham Connection would not have to pay a second initial charge in order to obtain an expanded connection. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

The Exchange believes that it is reasonable that the charge be the same whether the purchaser opts to connect to one or both Canadian access centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is reasonable to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is reasonable to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together and both

are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that it is reasonable and would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule.

The Proposed Change Is Equitable and Not Unfairly Discriminatory

The Exchange believes that the proposed change provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers because the change would mean that a customer would receive an expanded service, with the option of adding connectivity to two Canadian access centers for the same price that the Exchange currently charges for a connection to one Canadian access center.

Customers that currently have a Markham Connection would not have to pay a second initial charge in order to also obtain a TR2 Connection of the same size. As is currently true for Markham Connections, a customer that purchased a new connection would have its first month's MRC waived.

Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory since, as is true now, only customers that purchased the proposed service would be charged for it. The proposed change would not apply differently to distinct types or sizes of market participants but would apply to all customers equally. Moreover, although the Exchange proposes to expand the connectivity options, a customer that currently has a Markham Connection would not be obligated to make any changes. As is currently the case, the purchase of any connectivity service would be completely voluntary.

The Exchange believes that it is equitable and not unfairly discriminatory that the charge be the same whether the purchaser opts to connect to one or both Canadian access

centers. The size of the connection, not the number of Canadian access centers it leads to, factors into setting the price. First, the Exchange believes it is equitable and not unfairly discriminatory to view the expanded service as one service, and not two. Whether a purchaser connects to one or both Canadian access centers, the southbound connection is limited in size to the total bandwidth of the circuit. At the same time, northbound both access centers will receive all data sent on the connection. Second, the Exchange believes it is equitable and not unfairly discriminatory to base its cost on the size of the wireless bandwidth connection, not the number of Canadian access centers it reaches. If one customer wishes to use more of the wireless connection than its current circuit allows, it would need to increase the size of its circuit, and so its cost would increase. Markham and TR2 are geographically close together, and both are important access centers, so the network was designed to connect to both locations. Accordingly, it is the size of the circuit, not the number of Canadian access centers, that matters to the Exchange.

The Exchange believes that the proposed wireless connection between MDC and TR2 would be the first commercially available wireless connection between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would be equitable and not unfairly discriminatory because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to add the proposed wireless connectivity note. The Exchange believes that adding such text would alleviate any possible customer confusion as to how the connections between the MDC and Canadian access centers would work. In this way, it would enhance the clarity and transparency of the Connectivity Fee Schedule, making it easier to read and understand and alleviating possible customer confusion for all market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying

any applicable co-location fees, requirements, terms, and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act¹⁶ because it is not designed to address any competitive issues. The proposed rule change would provide customers with a wider range of choices for wireless connectivity to Canada.

The Exchange believes the wireless connections between MDC and TR2 are the first commercially available wireless connections between the two points, creating a new connectivity option for customers. The Exchange believes that creating such a connection would not impose any burden on competition that is not necessary or appropriate because market participants may create their own proprietary or commercial wireless connections between the two points. The Exchange could not impose any impediments to a third party seeking to offer a similar service, including by placing them at a latency or other competitive disadvantage with respect to the Exchange. Indeed, a third party has announced that it plans to create a wireless connection between Markham and the MDC and the Exchange believes it intends to expand its offering to connect to the TR2, underscoring that the Exchange could not impose any impediments to a third party providing wireless connectivity.

The proposed rule change would provide customers the ability to connect to a second Canadian data center for the same price they currently pay to connect to one. All customers would be able to choose if they want connections to one or both Canadian data centers and the size of connection they want. The Exchange does not believe that the proposed rule change would place any customer at a relative disadvantage compared to other customers.

For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸ Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and Rule 19b-4(f)(6)(iii) thereunder.²⁰

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)²¹ of the Act 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:

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6).

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) 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.

²¹ 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2024-05 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-NYSE-2024-05. 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 (<https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2024-05 and should be submitted on or before March 8, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-03225 Filed 2-15-24; 8:45 am]

BILLING CODE 8011-01-P

²² 17 CFR 200.30-3(a)(12).

¹⁶ 15 U.S.C. 78f(b)(8).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20188 and #20189;
MICHIGAN Disaster Number MI-20008]

**Presidential Declaration of a Major
Disaster for the State of Michigan**

AGENCY: U.S. Small Business
Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the
Presidential declaration of a major
disaster for the State of Michigan
(FEMA-4757-DR), dated 02/08/2024.
Incident: Severe Storms, Tornadoes,
and Flooding.
Incident Period: 08/24/2023 through
08/26/2023.

DATES: Issued on 02/08/2024.

*Physical Loan Application Deadline
Date:* 04/08/2024.

*Economic Injury (EIDL) Loan
Application Deadline Date:* 11/08/2024.

ADDRESSES: Visit the MySBA Loan
Portal at <https://lending.sba.gov> to
apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT:

Alan Escobar, Office of Disaster
Recovery & Resilience, U.S. Small
Business Administration, 409 3rd Street
SW, Suite 6050, Washington, DC 20416,
(202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is
hereby given that as a result of the
President's major disaster declaration on
02/08/2024, applications for disaster
loans may be submitted online using the
MySBA Loan Portal <https://lending.sba.gov>
or other locally announced
locations. Please contact the SBA
disaster assistance customer service
center by email at
disastercustomerservice@sba.gov or by
phone at 1-800-659-2955 for further
assistance.

The following areas have been
determined to be adversely affected by
the disaster:

*Primary Counties (Physical Damage and
Economic Injury Loans):*

Eaton, Ingham, Ionia, Kent,
Livingston, Macomb, Monroe,
Oakland, Wayne.

*Contiguous Counties (Economic Injury
Loans Only):*

Michigan: Allegan, Barry, Calhoun,
Clinton, Genesee, Gratiot, Jackson,
Lapeer, Lenawee, Montcalm,
Muskegon, Newaygo, Ottawa,
Shiawassee, St. Clair, Washtenaw
Ohio: Lucas

The Interest Rates are:

For Physical Damage:

Homeowners with Credit Avail- able Elsewhere	5.000
Homeowners without Credit Available Elsewhere	2.500

Businesses with Credit Avail- able Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	2.375
Non-Profit Organizations with- out Credit Available Else- where	2.375
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations with- out Credit Available Else- where	2.375

The number assigned to this disaster
for physical damage is 201886 and for
economic injury is 201890.

(Catalog of Federal Domestic Assistance
Number 59008)

Francisco Sánchez, Jr.,

*Associate Administrator, Office of Disaster
Recovery & Resilience.*

[FR Doc. 2024-03307 Filed 2-15-24; 8:45 am]

BILLING CODE 8026-09-P

DEPARTMENT OF STATE

[Public Notice: 12331]

**U.S. Department of State Advisory
Committee on Private International
Law: Notice of Annual Meeting**

The Department of State's Advisory
Committee on Private International Law
(ACPIL) will hold its annual meeting in
hybrid format on Thursday, March 21,
2024, at The George Washington
University (GWU) Law School, Faculty
Conference Center, Washington, DC
20052. The program is scheduled to run
from 9 a.m. to 4 p.m.

The meeting will include discussions
on international dispute resolution,
family law, and other international
commercial matters. It will also address
private international law developments
over the last year and possible future
work. If time allows, other topics of
interest may be discussed.

Time and Place: The meeting will
take place on Thursday, March 21, 2024,
GWU Law School, Faculty Conference
Center, 716 20th Street NW,
Washington, DC 20052 from 9:00 a.m. to
4:00 p.m. Those who cannot participate
by either in-person or virtual format but
wish to comment are welcome to do so
by email to Joseph Khawam at PIL@state.gov.

Public Participation: This meeting is
open to the public. There is currently no
COVID masking mandate, but anyone is
free to wear a mask.

Priority for in-person seating will be
given to members of the Advisory

Committee, and remaining seating will
be reserved based upon when persons
contact pil@state.gov. Those persons
planning to attend should provide their
name, affiliation, and contact
information to pil@state.gov no later
than March 7, 2024, stating in their
response whether they will attend in-
person or virtually. Room information
for in-person attendance and a Zoom
link for virtual attendance will be
provided following registration. When
registering, please indicate whether
attending in-person or via Zoom. If
attending virtually, please indicate if
you require captioning.

Persons needing reasonable
accommodation should notify pil@state.gov not later than March 14, 2024.
Requests made after that date will be
considered but might not be able to be
fulfilled. A more detailed agenda will be
available to registered participants in
advance of the meeting. Persons who
wish to have their views considered are
encouraged, but not required, to submit
written comments in advance.
Comments should be sent electronically
to pil@state.gov.

Joseph N. Khawam,

*Attorney-Adviser, Executive Director of
ACPIL, Office of Private International Law,
Office of the Legal Adviser, Department of
State.*

[FR Doc. 2024-03238 Filed 2-15-24; 8:45 am]

BILLING CODE 4710-08-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36741]

**Union Pacific Railroad Company—
Operation Exemption—in Tooele
County, Utah**

On November 21, 2023, Union Pacific
Railroad Company (UP) filed a petition
under 49 U.S.C. 10502(a) for exemption
from the prior approval requirements of
49 U.S.C. 10901 to reinstitute common
carrier service over an approximately
1.04-mile portion of rail line known as
the Warner Branch, between milepost
0.0 connecting to the Shafter
Subdivision and milepost 1.04, in
Tooele County, Utah (the Line). On
December 11, 2023, BNSF Railway
Company (BNSF) moved for the Board
to instead institute a proceeding under
49 U.S.C. 10502(b) and set a procedural
schedule for consideration of UP's
petition. As discussed below, the Board
will grant UP's petition and deny
BNSF's motion.

Background

According to UP, the Warner Branch
was formerly owned and operated by its

predecessor, Western Pacific Railroad Company (WP). (UP Pet. 2.) In 1983, WP sought and received authority to abandon the Warner Branch in *Western Pacific Railroad—Abandonment Exemption—in Tooele County, Utah*, FD 30208 (ICC served Aug. 9, 1983). (UP Pet. 2.) UP says that it is seeking to reinstitute common carrier service over the Line as part of a transaction with Savage Tooele Railroad Company (STR), in which UP agreed to sell STR the right-of-way and track assets between milepost 1.04 and milepost 6.94 of the Warner Branch so STR could construct approximately 11 miles of new rail line connecting to the Warner Branch to serve shippers located at Lakeview Business Park and connect to the national rail network.¹ (UP Pet. 2–3). UP further states that it did not want to sell the Line to STR because it has been using it as ancillary track to support operations on the Shafter Subdivision. (*Id.* at 3.)

In its December 11 motion, BNSF states that, as a condition of the Board's 1996 approval of the merger between UP and the Southern Pacific Rail Corporation (SP),² it was granted trackage rights to operate over the Shafter Subdivision and the right to interchange with any new short line railroad connecting to the Shafter Subdivision. (BNSF Mot. 1.) BNSF argues that it appears UP structured its transaction with STR in such a way as to establish a physical barrier between the Shafter Subdivision and STR so that BNSF cannot interchange with STR, as BNSF asserts it is entitled to do under the UP/SP merger conditions and the Restated and Amended Settlement Agreement (RASA) between UP and BNSF, which the Board approved in the context of its review of the merger transaction. (*Id.* at 1–2.)

¹ STR's petition to construct the new line is currently before the Board in *Savage Tooele Railroad—Construction & Operation Exemption—Line of Railroad in Tooele County, Utah*, Docket No. FD 36616. STR had originally indicated that either UP would retain ownership of the Line for use as ancillary track or STR would acquire the Line and reinstate common carrier service over it. STR Pet. 4–5, June 30, 2022, *Savage Tooele R.R.*, FD 36616. After the Board questioned how STR's proposed line would connect (and remain connected) to the national rail network should UP continue to retain the Line as ancillary track under 49 U.S.C. 10906, and requested supplemental information, see *Savage Tooele R.R.—Construction & Operation Exemption—Line of R.R. in Tooele Cnty., Utah*, FD 36616, slip op. at 2 (STB served Aug. 24, 2022), STR confirmed that UP decided to retain ownership of the Line and petition to reinstate common carrier operating authority over this segment, STR Verified Suppl. at 1, Sept. 20, 2022, *Savage Tooele R.R.*, FD 36616.

² See *Union Pac. Corp.—Control & Merger—S. Pac. Rail Corp.*, 1 S.T.B. 233, 419 (1996).

UP and STR separately replied to BNSF's motion on January 10, 2024. UP asks the Board to deny BNSF's motion, asserting that it has not violated BNSF's rights and that BNSF can demand arbitration under the RASA's arbitration provision if BNSF believes its rights were violated by UP. (UP Reply 4–5.) STR does not take a position on the merits of BNSF's motion but asks the Board to deny the motion because considering BNSF's claim and the relief it seeks in the context of this exemption proceeding would significantly prolong the proceeding and delay the rail construction project, thereby delaying STR's ability to meet the needs of rail shippers locating in Lakeview Business Park. (STR Reply 4.)

Discussion and Conclusions

BNSF's Motion. BNSF asks the Board to institute a proceeding under 49 U.S.C. 10502(b) and set a procedural schedule for consideration of UP's petition. BNSF maintains that UP structured its transaction with STR and acted with respect to the Line so that BNSF cannot interchange with STR, thus violating its rights under the RASA. (BNSF Mot. 1–2.) According to BNSF, "UP's action is consistent with other recent attempts by UP to frustrate the competition-preserving conditions imposed by the Board in connection with its approval of the UP/SP merger." (*Id.* at 2.)

UP's effort to seek common carrier operating authority over the Line is separate and distinct from BNSF's claimed right to access STR and its future shippers via the Line under the terms of the RASA. See *Union Pac. R.R.—Operation Exemption—in Bexar & Wilson Cntys., Tex.*, FD 35776, slip op. at 3–4 (STB served Dec. 24, 2013). BNSF itself has stated that it "believes that, regardless of the ownership or regulatory status of the [Line], BNSF should have the right to interchange with STR once the new short[] line begins operating, consistent with STR's stated intent and UP's obligations under RASA Section 8(k) and the UP/SP merger conditions." (BNSF Mot. 3.) Granting UP the authority to reinstitute common carrier service over the Line does not preclude BNSF from seeking, through either arbitration or a new, separate Board proceeding, a determination that BNSF is entitled to access STR via the Line. Moreover, granting UP common carrier operating authority over the Line will help avoid delay to STR's project and ensure that its business park shippers are connected to the national rail network. The Board notes that, in any future proceeding, whether before an arbitrator or the

Board, this decision shall not be construed as permitting UP to defeat any rights that BNSF may have had to interchange with STR or serve shippers at Lakeview Business Park had the exemption not become effective.

BNSF's motion to institute a proceeding and set a procedural schedule will therefore be denied.

UP's Petition for Exemption. Under 49 U.S.C. 10901, a rail carrier may not reinstitute operations over abandoned rail line without the prior approval of the Board. However, under 49 U.S.C. 10502(a), the Board shall, to the maximum extent consistent with 49 U.S.C. subtitle IV, part A, exempt a transaction or service from regulation upon finding that: (1) regulation is not necessary to carry out the rail transportation policy of 49 U.S.C. 10101 (RTP); and (2) either (a) the transaction or service is of limited scope, or (b) regulation is not needed to protect shippers from the abuse of market power.

Detailed scrutiny of the proposed transaction through an application for review and approval under 49 U.S.C. 10901 is not necessary to carry out the RTP. Reinstitution of service on the Line would facilitate rail transportation to tenants of the Lakeview Business Park and thus promote the RTP by minimizing the need for federal regulatory control (49 U.S.C. 10101(2)), ensuring the development and continuation of a sound rail transportation system with effective competition among rail carriers and with other modes, to meet the needs of the public (49 U.S.C. 10101(4)), reducing regulatory entry and exit barriers (49 U.S.C. 10101(7)), and providing for the expeditious handling and resolution of proceedings (49 U.S.C. 10101(15)). Other aspects of the RTP would not be adversely affected.

Regulation of this transaction is not needed to protect shippers from the abuse of market power. Rather, reinstitution of service is a step toward providing the shippers at Lakeview Business Park with a rail transportation option that otherwise would not exist. See *Savage Tooele R.R.—Constr. & Operation Exemption—Line of R.R. in Tooele Cnty., Utah*, FD 36616, slip op. at 2 (STB served Aug. 24, 2022) ("[I]t is not clear how STR's proposed line will connect (and remain connected) to the national rail network" should UP "retain the right-of-way between milepost 0.0 and milepost 1.04 to use as ancillary track. . . ."). And, as noted above, this decision does not affect BNSF's rights under RASA Section 8(k) and the UP/SP merger conditions. Moreover, the transaction is limited in

scope since the Line is only 1.04 miles long and reinstitution of common carrier service will merely connect STR's proposed line to the interstate rail network.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, labor protective conditions may not be imposed on transactions under 49 U.S.C. 10901. *See* 49 U.S.C. 10901(c).

UP states that the proposed action will not result in changes to existing rail carrier operations or existing operations on the Line that would exceed the applicable thresholds of 49 CFR 1105.7(e)(4) or (5). Therefore, under 49 CFR 1105.6(c), this transaction is categorically excluded from environmental review. Similarly, under 49 CFR 1105.8(b)(1), no historic report is required because the subject transaction is for reinstituted rail service, UP has indicated no plans to alter railroad properties 50 years old or older, and any abandonment of service would be subject to Board jurisdiction.

It is ordered:

1. BNSF's motion to institute a proceeding and set a procedural schedule is denied.

2. Under 49 U.S.C. 10502, the Board exempts UP's reinstitution of service over the Line from the prior approval requirements of 49 U.S.C. 10901.

3. Notice of the exemption will be published in the **Federal Register**.

4. The exemption will be effective on March 14, 2024.

5. Petitions to stay must be filed by February 23, 2024. Petitions for reconsideration and petitions to reopen must be filed by March 4, 2024.

6. This decision is effective on its service date.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Jeffrey Herzig,
Clearance Clerk.

[FR Doc. 2024-03305 Filed 2-15-24; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the

California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project on State Route 65, State Route 198 and State Route 245 from post miles 29.0–R30.4, R19.5–20.0 and 0.0–0.2 in Tulare County, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before July 15, 2024. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Jason Adair, Acting Senior Environmental Scientist, 2015 East Shields Avenue, Suite 100, Fresno, California 93726, (559) 383-5939, jason.adair@dot.ca.gov, Mon.–Fri. 9:00 a.m.–5:00 p.m.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans, has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Caltrans proposes to make operational improvements on State Route 65 from post miles 29.0 to R30.4, State Route 198 from post miles R19.5 to 20.0, and State Route 245 from post miles 0.0 to 0.2 in Tulare County.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA)/ Finding of No Significant Impact (FONSI) for the project, approved on December 29, 2023, and in other documents in the project records. The FEA, FONSI, and other project records are available by contacting Caltrans at the address provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act of 1969 (NEPA) [42 U.S.C. 4321–4335].

2. *Air:* Clean Air Act [23 U.S.C. 109(j) and 42 U.S.C. 7521(a)].

3. *Wildlife:* Federal Endangered Species Act [16 U.S.C. 1531–1543]; Fish and Wildlife Coordination Act [16 U.S.C. 661–666(C)]; Migratory Bird Treaty Act [16 U.S.C. 760c–760g].

4. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*].

5. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1344].

6. *Hazardous Waste:* Comprehensive Environmental Response, Compensation and Liability Act [42 U.S.C. 103]; Resource Conservation and Recovery Act of 1976 [42 U.S.C. 6901 *et seq.*].

7. *Social and Economic:* NEPA implementation [23 U.S.C. 109(h)]; Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)].

8. *Executive Orders:* E.O. 12898 Federal Actions to Address Environmental Justice and Low-Income Populations; E.O. 11988 Floodplain Management.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Antonio Johnson,

Director of Planning, Environmental and Right of Way, Federal Highway Administration, California Division.

[FR Doc. 2024-03229 Filed 2-15-24; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0062]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit

the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to extend an existing ICR titled, "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery." This ICR allows for ongoing, collaborative, and actionable communication between FMCSA and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management. The purpose of this notice is to allow 60 days for public comment before FMCSA submits its request to OMB.

DATES: Comments on this notice must be received on or before April 16, 2024.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2024–0062 using any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Roxane Oliver, FMCSA, Office of Analysis, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; 202–385–2324; Roxane.Oliver@dot.gov.

SUPPLEMENTARY INFORMATION:

Instructions

All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to <https://www.regulations.gov>, including any personal information

provided. Please see the Privacy Act heading below.

Public Participation and Request for Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2024–0062), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2024-0062/document>, click on this notice, click "Comment," and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

Privacy Act

In accordance with 44 U.S.C. 3506(c)(2)(A), DOT solicits comments from the public to better inform its information collection activities. 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.

Background: Executive Order 12862, "Setting Customer Service Standards," directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector (58 FR 48257, Sept. 11, 1993). To work continuously to ensure that our programs are effective and meet our customers' needs, FMCSA seeks to extend OMB approval of a generic clearance to collect qualitative feedback from our customers on our service delivery. The surveys covered in this generic clearance provide a way for

FMCSA to collect this data directly from our customers.

The proposed future information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback, we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with FMCSA's programs.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;

- The collections are noncontroversial and do not raise issues of concern to other Federal agencies;

- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

- Personally identifiable information is collected only to the extent necessary and is not retained;

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the Agency;

- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 2126–0049.

Type of Request: Renewal of a currently approved ICR.

Respondents: State and local agencies, the general public and stakeholders, original equipment manufacturers and suppliers to the commercial motor vehicle (CMV) industry, CMV fleet owners, CMV owner-operators, State CMV safety agencies, research organizations and contractors, news organizations, safety advocacy groups, and other Federal agencies.

Estimated Number of Respondents: 9,270.

Estimated Time per Response: Range from 5 to 30 minutes.

Expiration Date: August 31, 2024.

Frequency of Response: Generally, on an annual basis.

Estimated Total Annual Burden: 2,233 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB's clearance of this ICR.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2024–03257 Filed 2–15–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0143]

Request for Information: Drivers' Leasing Agreements for Commercial Motor Vehicles (CMVs)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice; request for information.

SUMMARY: FMCSA requests information from the public, including commercial motor vehicle (CMV) drivers, to assist the Agency's Truck Leasing Task Force (TLTF) in reviewing such leases to identify terms and conditions that may be unfair to drivers. The Infrastructure Investment and Jobs Act, (IIJA), or Bipartisan Infrastructure Law (BIL), requires the Secretary of Transportation, in consultation with the Secretary of Labor, to establish TLTF to examine the terms, conditions, and equitability of common truck leasing arrangements, particularly as they impact owner-operators and trucking businesses subject to such agreements. TLTF will examine these issues and submit a report to the Secretary of Transportation, the Secretary of Labor, and Congress on the TLTF's identified issues and conclusions regarding truck leasing arrangements, including recommended best practices. Comments submitted in response to this notice will

be shared with the TLTF prior to its next public meeting.

DATES: Comments must be received on or before March 18, 2024.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2023–0143 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov/docket/FMCSA-2023-0143/document>. Follow the online instructions for submitting comments.

- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

- *Submissions Containing Confidential Business Information (CBI):* Brian Dahlin, Chief, Regulatory Evaluation Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

To avoid duplication, please use only one of these four methods. See the “Confidential Business Information” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Shannon L. Watson, Senior Advisor to the Associate Administrator for Policy and Deputy Designated Federal Officer, Truck Leasing Task Force (TLTF), Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 360–2925; TLTF@dot.gov. If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

A. Submitting Comments

If you submit a comment, please include the docket number for this request for information (RFI) (FMCSA–2023–0143), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone

number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2023-0143/document>, click on this RFI, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

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 responsive to the RFI contain commercial or financial information that is customarily treated as private, that you actually treat as private, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as “PROPIN” to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the RFI. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Analysis Division, Office of Policy, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this RFI as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2023-0143/document> and choose the document to review. To view comments, click this RFI, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

DOT posts comments received, 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.transportation.gov/privacy. The comments are posted without edit and are searchable by the name of the submitter.

I. Background

Congress established the TLTF as a statutory committee under the authority of section 23009 of the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58 (2021). The TLTF is a Federal advisory committee established in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. app. 2. TLTF is tasked with examining and reviewing the terms, conditions, and equitability of common truck leasing arrangements, particularly as they impact owner-operators and trucking businesses subject to such agreements. Consistent with the above statutory authority, TLTF will also examine financing arrangements among motor carriers, entry-level drivers, driver training providers, and other involved entities, which may result in new drivers entering the trucking workforce encumbered by outsized debt and inequitable terms for repayment and will identify potential illegal practices to law enforcement or regulators, as appropriate. The Task Force will provide advice and recommendations to the Secretary of Transportation and Secretary of Labor through the Administrator of the Federal Motor Carrier Safety Administration (FMCSA) or their designee. For more information about TLTF, please visit <https://www.fmcsa.dot.gov/tltf>.

During the TLTF’s public meeting on January 18, 2024, TLTF members identified questions they would like to ask CMV drivers who may have been subject to inequitable or predatory terms, as well as questions for drivers who have had positive CMV leasing experiences and what separated the good from the bad experiences.

II. Request for Public Comments

FMCSA requests information from the public about leasing arrangements they have personally experienced or of which they have knowledge. FMCSA is particularly interested in hearing from CMV drivers, lessors of CMVs, trucker organizations, social services organizations, consumer rights and advocacy organizations, plaintiffs’

attorneys, academics and researchers, representatives of labor organizations, and state and local government officials. The list of questions provided below are examples of the information the TLTF would find helpful in completing its work. Commenters are not required to answer every question and commenters should not view the list as a constraint on sharing information with the Agency and its TLTF.

In addition to providing the information to the TLTF members, as mentioned above, FMCSA will share the information with the Consumer Financial Protection Bureau (CFPB), a U.S. government agency dedicated to making sure consumers are treated fairly by banks, lenders, and other financial institutions. The DOT has named the CFPB as a technical advisor to the TLTF. Please note that because the information is being submitted to a public docket accessible to all interested parties, individuals should redact personally identifiable information (PII), such as social security numbers, driver’s license number, personal address, etc.

Lessees of CMVs

1. If you signed a lease-purchase agreement for a CMV, could you provide copies of leasing documents and copies of documents for all other financial products associated with your work as a CMV lessee (*i.e.*, training debt, maintenance debt, earned wage access, contact from debt collectors, etc.)?

2. What were the actual terms of the lease (*e.g.*, minimum weekly or monthly payments and their structure, start and completion dates, make/model/year of the truck, depreciation and amortization, mileage at the start and conclusion of the lease, maintenance responsibilities, etc.)? Was the lease-purchase agreement held by a carrier or a third-party entity?

3. How was the lease-purchase agreement marketed to you? What were you told about the value of the truck and what earnings and work conditions you could expect? Were you evaluated for likelihood of repayment, through a credit or background check or some other method? What options existed for you to obtain the truck besides leasing it? Did other drivers have a different set of options? If so, why?

4. What did you understand, or not understand, about the terms and conditions to which you agreed? These terms may include the history, condition, and maintenance needs of the truck you leased. Prior to signing your lease-purchase agreement, did you have time to read and understand the leasing contract? Did you know the cost of credit (*e.g.*, interest rate or rent

charge) before signing the lease purchase agreement? Did you have a clear picture of your responsibility in the case of a major mechanical breakdown of the CMV?

5. Were you able to negotiate the terms? Were you provided any information about other financing alternatives? Did other drivers have a different set of options and if so, why?

6. Were you informed of how the motor carrier works with independent contractors vs. company drivers and lease-purchase drivers when business is slow? Are you treated similarly or is there a difference between the assignment of loads, etc.?

7. Please elaborate on any additional restrictions placed on your use of the CMV or additional financial agreements imposed outside of the written lease agreement. Did they encompass take-home pay, driver access to loads, etc.?

8. Please elaborate on any additional financial products associated with your work as a CMV lessee (e.g., training debt, maintenance debt, earned wage access, contact from debt collectors, etc.). For instance, if you took out maintenance debt, were you required to use the title of your CMV as security?

9. Were you able to successfully complete the terms of your lease-purchase agreement? If you did not complete your lease, why? How much did you owe at the completion of your lease? Were any charges assessed related solely to your lease payment or were there other charges, such as repayment of a maintenance bill or loan? If there were other charges, please explain.

10. If you owe a balance on your lease-purchase agreement, are you being contacted by the motor carrier, third-party debt collectors, or finance companies? Are there processes, policies, and procedures for taking and handling disputes about the debt? Has information about your debt been furnished to credit reporting companies or employment screening companies? Have you been threatened with a lawsuit to collect these debts? Do collection efforts cease when a driver files for bankruptcy or obtains bankruptcy discharge?

11. How did your expectations about the benefits of the lease compare to the reality of working under that lease? What have the effects of your lease-purchase agreement been on your finances, employment experience, professional mobility, workplace health and safety, and family's well-being?

Lessors of CMVs

1. If you are or were a lessor of CMVs, what best practices do, or did you implement or recommend to ensure that

all leases of CMVs you provide are fair and just? Do you underwrite leases? If so, how? How do you determine the value of a CMV and the expected depreciation? If your lessees are pleased with the terms you provide, please expound on those terms.

2. If you lease CMVs to drivers but do not own the CMV (e.g., the CMV is being financed by your company and then you lease it to a driver), how do you determine how much to charge the driver under the lease agreement and how do you ensure the driver can ultimately own the vehicle if there is a lease-purchase agreement?

3. Do you have any specific agreements available to drayage drivers at ports relating to the Clean Truck Program or any similar program to decrease emissions from port operations? Do you have any data that would show the impact of truck leasing agreements on the net compensation of CMV drivers, including port drayage drivers?

Sue Lawless,

Acting Deputy Administrator.

[FR Doc. 2024-03205 Filed 2-15-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2023-0172]

Agency Information Collection Activities; Approval of a New Information Collection Request: Impact of Driver Detention Time on Safety and Operations

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval.

This notice invites comments on a proposed information collection titled *Impact of Driver Detention Time on Safety and Operations*. This research study will collect data on commercial motor vehicle (CMV) driver detention time representative of the major segments of the motor carrier industry, analyze that data to determine the frequency and severity of detention time, and assess the utility of existing

intelligent transportation systems (ITS) solutions to measure detention time. Approximately 80 carriers and 2,500 CMV drivers will provide data in the study. The study will provide a better understanding of the impact of driver detention time on driver safety and CMV operations and inform strategies that may be used to mitigate driver detention time. The number of public comments received in response to the 60-day FR notice was 171.

DATES: Comments on this notice must be received on or before March 18, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Dan Britton, Mathematical Statistician, Office of Research and Registration, DOT, FMCSA, 6th Floor, West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001; 202-366-9980; dan.britton@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Impact of Driver Detention Time on Safety and Operations.

OMB Control Number: 2126-00XX.

Type of Request: New ICR.

Respondents: CMV carriers and drivers.

Estimated Number of Respondents: 80 CMV carriers and 2,500 CMV drivers.

Estimated Time per Response: 30 seconds (for drivers and CMV carrier operation team).

Expiration Date: This is a new ICR.

Frequency of Response: Once per delivery/pick-up.

Estimated Total Annual Burden: 7,869.17 hours.

Background

"Detention time" refers to the extra time CMV operators wait at shipping and receiving facilities due to delays not associated with the loading and unloading of cargo. Drivers are often not paid for this extra time. Although there is currently no standard definition of detention time, the CMV industry, the U.S. Government, and academic researchers in the United States have previously used dwell time—the total amount of time spent at a facility—exceeding 2 hours to define when detention time occurs.

Detention time in the CMV industry is a longstanding issue and consistently ranks as one of the top problems for a large portion of CMV operators on an

ongoing basis. Further, detention time often results in lost revenue for many drivers and carriers. Reducing detention time may reduce costs for carriers, increase pay for drivers, and improve CMV drivers' ability to make deliveries on time or arrive at a destination as planned without violating hours of service (HOS) requirements. Finally, drivers who experience less detention time may be more likely to drive safely to reach their destinations within the HOS limits and less likely to operate beyond HOS limits and improperly log their driving and duty time to make deliveries on time.

An important first step in addressing detention time is understanding the factors that contribute to the issue. FMCSA completed a study in 2014 on the impact of detention time on CMV safety. Although this study provided valuable initial insights, it had several limitations, including a small sample of mostly large carriers, a rudimentary estimation of detention time, the inability to identify time spent loading/unloading, and data that did not cover an entire 12-month period. Therefore, FMCSA needs additional data from a broader sample of carriers to understand the safety and operational impact of detention time, to better understand why detention time occurs, and to identify potential mitigation strategies the CMV industry may use to reduce detention time while improving operational efficiencies and safety.

The purpose of obtaining data in this study is to evaluate the impact of driver detention time on safety and CMV operations. Specifically, there are three primary objectives for the data collection in this study: (1) assess the frequency and severity of driver detention time using data that represent the major segments of the motor carrier industry; (2) assess the utility of existing ITS solutions to measure detention time; and (3) prepare a final report that summarizes the findings, answers the research questions, and offers strategies to reduce detention time. Completing these research objectives will provide insight into any relationship between driver detention time and CMV safety. Additionally, the findings from this study can contribute to a more complete understanding of these issues and facilitate private sector decisions that lead to reductions in detention time and improvements in safety and supply chain efficiency.

The study includes data collection via electronic logging devices (ELDs), transportation management systems (TMS), vehicle telematic systems, safety records, and answers to questions delivered through the carriers'

dispatching systems. The ELD, TMS, telematics, and safety data are already collected by carriers. The only additional data that will be collected will be the answers to questions submitted through the carriers' dispatching systems. This information will allow FMCSA to identify the severity and frequency of detention time, the factors that contribute to detention time, and the administrative, operational, and safety outcomes of detention time. After agreeing to participate in the study, carriers will collect and provide 12 months of data.

The carriers will be selected so that the sample is representative of the nation. Carriers will be selected from those who use an ELD, TMS, and telematics device or app that is integrated with the research team's data collection system for delivery/pickup details, telematics and vehicle tracking metrics, and ELD data. However, the study may include other carriers that express interest in participating if they use an ELD, TMS, and telematics device that can be integrated with the research team's system to collect data. These data are critical to answer the research questions. The final sample from this source will include up to 80 carriers with up to 2,500 total vehicles. This sample will include a variety of carrier operations, including long haul/short haul, private/company fleets and for-hire fleets, port servicing (primarily chassis), owner-operators, hourly and mileage-based operators, truckload/less-than-truckload, and dedicated local delivery. These carriers will range in size from single-vehicle owner-operators to carriers with hundreds of trucks, with a likely average fleet size of approximately 30 vehicles. Multiple analyses will be performed, including assessing the relationships between detention time and characteristics of carriers, facility locations, and driver schedules (appointment times, time of day, day of week, month, and season). Measures of detention time will include the number of detained stops per shift and the duration of each detention. Regression models will be used to compare these variables for significant differences in associated detention time.

Another analysis will examine the relationship between detention time and safety outcomes during the shifts following the detention time. The relationships between detention time and safety outcomes will be evaluated by generalized linear models such as Poisson or negative binomial regression models. The independent variables will be the characteristics of detention time, such as detention time per shift. The response variable will be the number of

safety outcomes (e.g., crashes) that occurred during the subsequent shift. The driving time will be treated as an exposure variable to normalize crash risk with respect to driving time.

Finally, the study will estimate the cost per year associated with detention time, including lost productivity, disruptions to the supply chain, and any increases in fatal, injury, and property-damage-only crashes.

FMCSA published the 60-day **Federal Register** notice on August 24, 2023, and the comment period closed on October 24, 2023 (88 FR 58060). A total of 171 comments were received from the public. These comments revolved around 11 issues, with many comments covering more than one issue, to varying degrees: (1) the relationship between detention time and driver compensation; (2) organizational issues at the shipper/receiver, carrier, and/or broker; (3) the relationship between detention time and pick-up/delivery appointment times; (4) examples of detention time characteristics as experienced by commenters; (5) the relationship between detention time and HOS regulations; (6) the impact of detention time on logistics and the economy; (7) the impact of detention time on driver welfare; (8) the impact of detention time on driver and roadway user safety; (9) suggestions and support for detention time-related regulations; (10) considerations for defining and quantifying detention time and collecting necessary data; and (11) general support for the study. Responses to these issues are provided below. Many comments touched on multiple issues; however, the responses below are organized based on the primary feedback provided.

The Relationship between Detention Time and Driver Compensation

Two-thirds of the comments described a relationship between detention time and driver compensation. The comments included descriptions of current pay structures, including driver pay modality (i.e., pay by mile, load, or hour) and detention-specific compensation (e.g., pay per detainment, maximum pay, proportion of detainment-related pay received by driver, etc.). The comments reflected hypotheses that current pay structures impact detention frequency and severity and that detention frequency and severity, in turn, also affect driver compensation. Several comments also included proposed compensation approaches to address detention frequency and severity and the resulting financial impacts on drivers.

FMCSA believes it is important to understand the relationship between driver compensation and detention time. An assessment of driver compensation and safety and other driver-related factors (including detention time) is the focus of a separate study sponsored by FMCSA and conducted by the Transportation Research Board. The study outlined in this notice is focused on the relationship between driver detention time, safety, and operations. FMCSA believes these studies will complement each other and provide vital information on detention time.

Organizational Issues at The Shipper/Receiver, Carrier, and/or Broker

A total of 78 comments described organizational issues at the shipper/receiver, carrier, and/or broker level and their impacts on detention time. These comments included inefficiencies at shippers/receivers that increase detention time (e.g., understaffed shipper/receiver facilities leading to backups in loading/unloading; difficult driver check-in procedures adding to time spent at a facility; products being processed at loading, which extends the loading time; shippers/receivers not honoring appointment times; lack of room in storage facilities for products to be unloaded; appointment times scheduled for facility shift changes or breaks; and overloading the truck). Comments also described poor communication and unequal power dynamics between shippers/receivers, drivers, and carriers/brokers regarding expected loading/unloading times and detention times. Several comments described difficulties obtaining verified documentation of detention time due to complicated paperwork and concern for adding waiting time to have paperwork completed. A few comments touched on leased warehouses and the potential impact on detention time.

These comments illustrate the need to collect data on loading/unloading time, active dwell time, and detention time. The study outlined in this notice will collect this data through multiple methods: driver self-report, TMS data (such as shipper/receiver, order pick-up/delivery locations, appointment time, billed amount for detention time, etc.), and telematics/ELD data (such as latitude and longitude and duty status). In addition, analyses in the study will consider carrier fleet size, operation type, geographic location, time of year, facility type, and other key features to determine their impacts on detention time and safety. Some comments proposed solutions to reduce detention time, but the study will only collect data

on detention time as it occurs, without attempting to determine the effectiveness of alternative methods of reducing detention time.

The Relationship Between Detention Time and Pick-Up/Delivery Appointment Times

A total of 27 comments touched on the relationship between detention time and pick-up/delivery appointment times. The comments included discussions of appointment times not being honored at pick-up/delivery locations, unrealistic scheduled appointment times, and the impact of detention time on the remaining pick-up/delivery appointment times scheduled for the day or week. The study will collect data on appointment times (if applicable) through the carriers' TMS. The data will be analyzed to assess whether detention time varies for pick-ups/deliveries with and without appointment times.

Shared Examples of Detention Time Characteristics as Experienced by Commenters

A total of 49 comments provided detailed examples of detention time as experienced by commenters, some describing typical situations, with others describing atypical but significant situations, including reports of detention time lasting 24 hours. The study will capture detention time reports from up to 2,500 drivers over a year of driving. The detention time data will be assessed to understand the full spectrum of detention time experienced by the participating carriers and drivers.

The Relationship Between Detention Time and Hours-of-Service Regulations

A total of 41 comments described the relationship between detention time and HOS regulations. At a high level, HOS regulations provide legal boundaries on daily and weekly driving and working hours. The comments described the difficulty in capturing detention time using standard HOS regulation duty statuses. When waiting at shippers/receivers, drivers often need to remain vigilant for their opportunity to load/unload, and they might use this time to perform non-driving work, which means they are not truly "off duty." However, remaining "on duty" for detention time can use a significant portion of drivers' regulated workday hours, limiting their opportunities to work or drive after they leave the shipper/receiver. After experiencing detention time, drivers also feel impacted by HOS limits when needing to drive to a safe resting location. Comments included discussion of falsifying logs after

detention time. The study will capture information on drive time, work time, and HOS-related violations through ELD data and driver self-reports via prompted electronic questions. Additionally, the study will collect data on all activity while the vehicle is at a delivery/pickup location to account for drivers who go off-duty while detained. These data will provide a better understanding of the relationship detention time has with HOS regulations.

Impact of Detention Time on Logistics and the Economy

Ten comments discussed the impact of detention time on logistics and the economy. Previous studies have estimated the impacts of detention time on industry earnings and society as a whole. The comments explained that detention time causes supply chain issues, impacts efficiency, and reduces time available to make additional pick-ups and deliveries, and can reduce the quality of goods, leading to products being rejected by the receiver upon delivery. Additionally, drivers often use fuel while waiting to load/unload. The study outlined in this notice will investigate the costs of driver detention time in terms of lost productivity and disruptions to the supply chain.

The Impact of Detention Time on Driver Welfare

There were 66 comments that discussed the impact of detention time on driver welfare. Drivers who experience detention time may find themselves unexpectedly needing to complete their route at night. Commenters reported not being allowed to rest while waiting to load/unload and not being allowed to rest at the shipper/receiver after detention time, forcing them to return to the roadway to find safe parking. Commenters mentioned that drivers are often not granted access to essential facilities, such as restrooms or vending machines (possibly as a coronavirus disease mitigation strategy), and yet they also cannot leave the shipper/receiver without risking their place in line. For all these reasons, detention time can increase fatigue and cause stress, frustration, and anger. Several comments discussed the Fair Labor Standards Act (FLSA), which regulates minimum wage and overtime pay for private and government employees. Drivers are exempt from FLSA laws. The impact of detention time on driver welfare, while outside the scope of the current study, is an important topic and may be examined in a follow-up study.

The Impact of Detention Time on Driver and Roadway User Safety

A total of 73 comments discussed the impact of detention time on driver and roadway user safety. After experiencing detention time, drivers may be inclined to drive aggressively and/or over the speed limits to stay within their HOS regulatory limits, arrive at the next appointment on time, or return home. The comments described how detention time can lead to fatigued driving, driving during hours outside a driver's regular schedule (such as at night), unpredictable sleep schedules, and road rage.

The study will capture information on safety-related events through insurance claims data, Federal crash data, telematics data, and driver self-reports via prompted electronic questions. The study will link the safety-related event data to detention time data and assess whether driver detention influences the likelihood of crashes and fatigue.

Suggestions and Support for Detention Time-Related Regulations

A total of 41 comments provided suggestions and/or support for detention time-related regulations, including potential regulations addressing driver pay, use of appointment times versus open pick-up/delivery windows, shipper/receiver facility maintenance and upgrades to improve efficiency, the use of leased warehouses, standardization of detention time documentation on pick-up/delivery-related paperwork, the FLSA, reasonable wait times, fines for shippers/receivers who go beyond a federally established wait time limit, and the creation of a Federal and/or publicly-accessible database that documents shipper/receiver detention time behavior. FMCSA believes the study outlined in this notice is essential to obtaining a full and updated understanding of detention time, which will help identify solutions to the problem.

Considerations for Defining and Quantifying Detention Time and Collecting Necessary Data

Five comments raised concerns regarding how to define detention time, accurately quantify detention time according to a standard definition, and collect the necessary data to conduct the study analyses. The definition of detention time has varied across industry, government, and research; however, it generally includes components regarding the time the driver has been at the shipper/receiver, the duty status of the driver, and

loading/unloading progress. The comments emphasized that the study needs to collect accurate data. The current study will collect detention time data through multiple methods: driver self-report, TMS data (such as shipper/receiver, order pick-up/delivery locations, appointment times, scheduled and planned arrival and departure times, billed amounts for detention time, etc.), and telematics/ELD data (such as latitude and longitude). The study will use GPS data and geofenced shipper/receiver facility data to obtain arrival and departure information.

One comment suggested broadening the sample universe to include more than one telematics service in FMCSA's carrier eligibility requirements. The comment also suggested expanding the sample universe to include carriers who do not use telematics services or ELDs. To collect the necessary data and answer the study research questions, carriers must use a telematics and ELD service. Since the 60-day **Federal Register** notice, FMCSA has partnered with one of the leading TMS, ELD, and telematics providers used by many small carriers. While the Agency may focus recruitment on clients of this service provider, the study documents have been revised to allow carriers using a different provider to participate if they meet the criteria and can integrate their platforms with the new technology provider.

Another comment emphasized the need to protect personal information shared by carriers and drivers in the study. Protecting participant data is of the utmost importance to FMCSA. The Agency will take all the necessary precautions to ensure the confidentiality of participant data. As part of this process, all drivers and carriers will be assigned anonymous identification numbers to link all datasets. Further, FMCSA will scrub all datasets of any information that could potentially identify participants. Identifying driver and carrier information will not be shared with the Agency.

One comment suggested the burden estimate was too low. However, the data management and cleaning tasks the commenter felt had not been accounted for will not be the responsibility of participating carriers. FMCSA will perform the additional data linking and cleaning tasks not included in the burden estimate. However, the Agency has removed the data collection task that asked carriers' operation teams to respond to questions each time an order is booked, scheduled, or dispatched. Information that would have been collected by these questions was determined to be redundant to

information collected via the automated data collection system, and using the automated data collection system to collect this information will reduce the burden on participating carriers.

Support for the Study

Thirteen comments specifically mentioned support for the study. The comments expressed the importance of collecting accurate and representative data, highlighting how updated detention time assessments could be utilized to address the frequency and severity of detention time. FMCSA believes this is an important study that will provide a critical and updated understanding of detention time across various segments of the industry.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,
Associate Administrator, Office of Research and Registration.

[FR Doc. 2024-03256 Filed 2-15-24; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2023-0265]

Agency Information Collection Activities; Revision of an Approved Information Collection: Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew the ICR titled, "Application for Certificate of Registration for Foreign

Motor Carriers and Foreign Motor Private Carriers,” OMB Control No. 2126–0019. Foreign (Mexico-based) for-hire and private motor carriers are required to file an application Form OP–2 if they wish to register to transport property within municipalities in the United States on the U.S.-Mexico international border or within the commercial zones of such municipalities. The Certificate of Registration only permits the holder to operate in the United States within these areas. A holder of a Certificate of Registration who operates a vehicle beyond these areas is subject to applicable penalties and out-of-service orders.

DATES: Comments on this notice must be received on or before April 16, 2024.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2023–0265 using any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments.

- **Mail:** Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.

- **Hand Delivery or Courier:** Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

- **Fax:** 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey L. Secrist, Office of Registration, Chief, Registration Division, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590; (202) 385–2367; jeff.secrist@dot.gov.

SUPPLEMENTARY INFORMATION:

Instructions

All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to <https://www.regulations.gov>, including any personal information

provided. Please see the Privacy Act heading below.

Public Participation and Request for Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2023–0265), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2023-0265/document>, click on this notice, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

Privacy Act

In accordance with 44 U.S.C. 3506(c)(2)(A), DOT solicits comments from the public to better inform its information collection activities. 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.

Background

Title 49 U.S.C. 13902(c) contains basic licensing procedures for registering foreign (Mexico-based) motor carriers to operate across the U.S.-Mexico international border into the United States. The regulations that require foreign (Mexico-based) motor carriers to apply to the FMCSA for a Certificate of Registration to provide interstate transportation in municipalities in the United States on the U.S.-Mexico international border or within the *commercial zones* of such municipalities as defined in 49 U.S.C. 13902(c)(4)(A) are found at 49 CFR part 368. FMCSA carries out this registration program under authority delegated by the Secretary of Transportation.

Foreign (Mexico-based) motor carriers with existing Certificates of Registration may continue to use Form OP–2 update their registration information with the FMCSA. The form requests information on the foreign motor carrier’s name, address, U.S. DOT number, form of business (e.g., corporation, sole proprietorship, partnership), locations where the applicant plans to operate, types of registration requested (e.g., for-hire motor carrier, household goods carrier, motor private carrier), insurance, safety certifications, household goods arbitration certifications, and compliance certifications.

Changes From Previous Estimates

The currently approved version of this ICR estimated the average annual burden to be 47 annual burden hours, with 31 total annual respondents. For this renewal, the estimated average annual burden is 878 hours, and 585 average annual respondents, based on an estimated burden of 1.5 hours per respondent. The estimated annual burden hour increase of 831 is due primarily to the increase in the number of updated OP–2 forms filed from 2020 through 2022. The average number of entities which filed updated OP–2 forms in the three-year period 2020 and 2022 increased by 95 percent compared to the number that registered from 2017 through 2019.

Title: Application for Certificate of Registration for Foreign Motor Carriers and Foreign Motor Private Carriers.

OMB Control Number: 2126–0019.

Type of Request: Renewal of a currently approved ICR.

Respondents: Foreign motor carriers.

Estimated Number of Respondents: 585.

Estimated Time per Response: 1.5 hours.

Expiration Date: October 31, 2024.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 878 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA’s functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB’s clearance of this ICR.

Issued under the authority of 49 CFR 1.87.
Thomas P. Keane,
*Associate Administrator Office of Research
and Registration.*
[FR Doc. 2024-03258 Filed 2-15-24; 8:45 am]
BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Advisory Council; Public Meeting

AGENCY: Maritime Administration, DOT
ACTION: Notice of public meeting.

SUMMARY: The U.S. Department of Transportation, Maritime Administration (MARAD) announces a meeting of the U.S. Merchant Marine Academy (USMMA) Advisory Council (Council). During the meeting, the USMMA leadership will provide an update on programs and priorities, including: governance, sexual assault and sexual harassment, academics, culture and diversity, and facilities and infrastructure.

DATES: March 7, 2024, from 9 a.m. to 12 p.m. EST.

Requests to submit written materials to be reviewed during the meeting must be received no later than February 23, 2024. Requests for accommodations for a disability must be received by February 29, 2024.

ADDRESSES: The meeting will be held through a virtual forum. Virtual meeting access information will be available on the USMMA Advisory Council web page and social media channels no later than March 1, 2024. General information about the Council is available on the MARAD web page at www.maritime.dot.gov/outreach/united-states-merchant-marine-academy-advisory-council.

FOR FURTHER INFORMATION CONTACT: The Council's Designated Federal Officer and Point of Contact, Mary Grice, 202-366-4264 or via email to USMMAAdvisoryCouncil@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Council is established pursuant to 46 U.S.C. 51323. The Council operates in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. app. 2.

The objective and scope of the Council is to provide independent advice and recommendations to the Secretary of Transportation (Secretary) on matters relating to the U.S. Merchant Marine Academy (USMMA) including

in the areas of curriculum development and training programs; diversity, equity, and inclusion; sexual assault prevention and response; infrastructure maintenance and redevelopment; midshipmen health and welfare; governance and administrative policies; and other matters.

II. Agenda

The agenda will be as follows:

1. Welcome and opening remarks
2. Updates by Academy leadership on priority programs
3. Public comment
4. Administrative items

III. Public Participation

This meeting is open to the public and will be held through a virtual forum. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Any member of the public is permitted to file a written statement with the Council. Written statements should be sent to the Designated Federal Officer listed in the **FOR FURTHER INFORMATION CONTACT** section no later than February 23, 2024.

Only written statements will be considered by the Council; no member of the public will be allowed to present questions or speak during the meeting unless requested to do so by a member of the Council.

(Authority: 46 U.S.C. 51323; 5 U.S.C. 552b; 5 U.S.C. App. 2; 41 CFR parts 102-3.140 through 102-3.165)

By Order of the Maritime Administrator,
T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2024-03287 Filed 2-15-24; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

[DOCKET No.: DOT-OST-2024-0011]

Guidance for the Acceptance and Use of Geomatic Information Obtained From a Non-Federal Entity

AGENCY: Office of the Secretary of Transportation, Department of Transportation.

SUMMARY: The U.S. Department of Transportation (DOT) is issuing guidance for the acceptance and use of geomatic information obtained from a non-Federal entity. The Infrastructure

Investment and Jobs Act, H.R. 3684, Title I Federal-Aid Highways, Subtitle C, directs the Secretary to develop guidance for the acceptance and use of geomatic information obtained from a non-federal entity. DOT's Geospatial Management Office (GMO) recognizes the need for a geomatic information standard to meet this requirement.

DATES: Comments are due by March 18, 2024.

ADDRESSES: You may send comments, identified by DOT-OST-2024-0011, by any of the following methods:

- Follow the instructions for sending comments on the <https://www.regulations.gov/>. Include DOT-OST-2024-0011 in the subject line of the message.

- *Mail:* Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery/Courier:* Room W12-140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov at any time or to Room W12-140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: "Comments on DOT-OST-2024-0011." The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to possible delays in the delivery of U.S. mail to federal offices in Washington, DC, we recommend that persons consider an alternative method (internet, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

FOR FURTHER INFORMATION CONTACT: Amy Nelson, Chief Geospatial Information Officer, OST, Department of Transportation at 202-366-9201 or by email at .

For specific inquiries on the Department's administration mechanisms for seeking correction of information covered by these guidelines, or for specific inquiries about the Department's statistical guidelines, please refer to the contacts listed in the guidelines.

SUPPLEMENTARY INFORMATION: Pursuant to The Infrastructure Investment and Jobs Act (Pub. L. 117–58), H.R. 3684, Title I Federal-Aid Highways, Subtitle C which directs the Secretary to develop guidance for the acceptance and use of geomatic information obtained from a non-federal entity, the Department has identified a standard to serve as guidance. The Project Development and Design Manual for Federal Lands Highways, maintained by the Western Federal Lands Highway Division, provides policies and guidance for project development and design activities related to Federal Lands Highways and can serve as guidance for similar projects. The manual was created in 1988 and is updated regularly. Additionally, it contains background and reference material, including specific information about techniques, theory, and specifications.

DOT will adopt Chapter Five of the Project Development and Design Manual for Federal Lands Highways (https://flh.fhwa.dot.gov/resources/design/pddm/Chapter_05.pdf) as the standard for the acceptance and use of geomatic information obtained from a non-federal entity. In instances where the manual's guidance does not apply to geomatic information obtained by a DOT Operating Administration (OA), the OA will have the flexibility to develop and maintain modal-specific geomatic information guidance.

Examples of existing modal-specific geomatic information guidance include:

(1) FAA Advisory Circulars which contain detailed requirements and standards for airport surveys and flight procedures. (examples: AC16B, AC17C, AC18B)

(2) PHMSA's Pipeline Operator Standards Manual (https://www.npms.phmsa.dot.gov/Documents/Operator_Standards.pdf), which defines positional accuracy requirements for gas transmission and hazardous liquid pipelines.

DOT is monitoring the development of candidates for geomatic guidance and will assess the need for updates to this policy statement.

The updated guidelines are available on the Department's website at https://flh.fhwa.dot.gov/resources/design/pddm/Chapter_05.pdf and in the docket. The Department seeks comment

on the guidelines and the proposed changes.

Issued in Washington, DC.

Cordell Schachter,

Chief Information Officer, Department of Transportation.

[FR Doc. 2024–02794 Filed 2–15–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[DOT–OST–2023–0137]

Advisory Committee on Transportation Equity (ACTE); Notice of Public Meeting

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: DOT OST announces a meeting of ACTE, which will take place via Zoom Webinar.

DATES: The meeting will be held Friday, March 1, 2024, from 2:30 to 4:30 p.m. Eastern Time. Requests for accommodations because of a disability must be received by Friday, February 23. Requests to submit questions must be received no later than Friday, February 23. The registration form will close on Thursday, February 29.

ADDRESSES: The meeting will be held via Zoom. Those members of the public who would like to participate virtually should go to <https://www.transportation.gov/mission/civil-rights/advisory-committee-transportation-equity-meetings-materials> to access the meeting, a detailed agenda for the entire meeting, meeting minutes, and additional information on ACTE and its activities.

FOR FURTHER INFORMATION CONTACT:

Sandra D. Norman, Senior Advisor and Designated Federal Officer, Departmental Office of Civil Rights, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (804) 836–2893, ACTE@dot.gov. Any ACTE-related request or submissions should be sent via email to the point of contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Purpose of the Committee

ACTE was established to provide independent advice and recommendations to the Secretary of Transportation about comprehensive, interdisciplinary issues related to civil rights and transportation equity in the planning, design, research, policy, and

advocacy contexts from a variety of transportation equity practitioners and community leaders. Specifically, the Committee will provide advice and recommendations to inform the Department's efforts to:

Implement the Agency's Equity Action Plan and Strategic Plan, helping to institutionalize equity into Agency programs, policies, regulations, and activities;

Strengthen and establish partnerships with overburdened and underserved communities who have been historically underrepresented in the Department's outreach and engagement, including those in rural and urban areas;

Empower communities to have a meaningful voice in local and regional transportation decisions; and

Ensure the compliance of Federal funding recipients with civil rights laws and nondiscrimination programs, policies, regulations, and activities.

Meeting Agenda

The agenda for the meeting will consist of:

Welcome and Opening remarks
ACTE Community Check-In
U.S. Department of Transportation updates
ACTE Research Report Findings
Upcoming ACTE Meetings
Closing remarks and Next Steps

Meeting Participation

Advance registration is required. Please register at <https://usdot.zoomgov.com/webinar/register/WN/UvxaMcB4QfWzvjChzd9yIQ> by the deadline referenced in the **DATES** section. The meeting will be open to the public for its entirety. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section. Questions from the public will be answered during the public comment period only at the discretion of the ACTE chair, vice chair, and designated Federal officer. Members of the public may submit written comments and questions to the point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section on the topics to be considered during the meeting by the deadline referenced in the **DATES** section.

Dated: February 9, 2024.

Irene Marion,

Director, Departmental Office of Civil Rights.

[FR Doc. 2024–03310 Filed 2–15–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY**Office of the Secretary****List of Countries Requiring Cooperation With an International Boycott**

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Iraq
Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
Yemen

Lindsay Kitzinger,

International Tax Counsel, (Tax Policy).

[FR Doc. 2024-03269 Filed 2&nnhjc vdash;15-24; 8:45 am]

BILLING CODE 4810-AK-P

DEPARTMENT OF THE TREASURY**Proposed Collection; Comment Request**

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on an information collection that is due for extension approval by the Office of Management and Budget. The Office of International Affairs of the Department of the Treasury is soliciting comments concerning extension without change of the following form: Treasury International Capital Form SLT, "Aggregate Holdings, Purchases and Sales, and Fair Value Changes of Long-Term Securities by U.S. and Foreign Residents." The report is mandatory.

DATES: Written comments should be received on or before April 16, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International

Portfolio Investment Data Systems, Department of the Treasury, Room 1050, 1500 Pennsylvania Avenue NW, Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Dwight Wolkow by email (comments2TIC@treasury.gov), or telephone (202-622-1276).

FOR FURTHER INFORMATION CONTACT:

Copies of the proposed forms and instructions are available on the Treasury's TIC Forms web page, <https://home.treasury.gov/data/treasury-international-capital-tic-system-home-page/tic-forms-instructions/tic-slt-form-and-instructions>. Requests for additional information should be directed to Mr. Dwight Wolkow, (comments2TIC@treasury.gov or 202-622-1276).

SUPPLEMENTARY INFORMATION:

Title: Treasury International Capital Form SLT, "Aggregate Holdings, Purchases and Sales, and Fair Value Changes of Long-Term Securities by U.S. and Foreign Residents."

OMB Control Number: 1505-0235.

Abstract: Form SLT is part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR 128) and is designed to collect timely information on international portfolio capital movements. Form SLT is a monthly report on cross-border portfolio investment in long-term marketable securities by U.S. and foreign residents. This information is used by the U.S. Government in the formulation of international financial and monetary policies and for the preparation of the U.S. balance of payments accounts and the U.S. international investment position.

Current Actions: No changes will be made in Form SLT or in the instructions for the form.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations. Form SLT (1505-0235).

Estimated Number of Respondents: 429.

Estimated Average Time per Respondent: Average 12 hours per respondent per filing. The estimated average burden per respondent varies widely, from about 21.6 hours per filing for a U.S.-resident custodian to about 9.3 hours for a U.S.-resident issuer or U.S.-resident end-investor.

Estimated Total Annual Burden Hours: 61,600 hours, based on 12 reporting periods per year.

Request for Comments: Comments submitted in response to this notice will

be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) Whether Form SLT is necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Reporting Systems.

[FR Doc. 2024-03323 Filed 2-15-24; 8:45 am]

BILLING CODE 4810-AK-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0859]

Agency Information Collection Activity: Education Benefit Entitlement Restoration Request Due To School Closure, Program Suspension or Withdrawal

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 16, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits

Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0859” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT:

Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email maribel.aponte@va.gov. Please refer to “OMB Control No. 2900–0859” in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA’s functions, including whether the information will have practical utility; (2) the accuracy of VBA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Pub. L. 115–48; title 38 U.S.C. 3699.

Title: Education Benefit Entitlement Restoration Request Due to School Closure, Program Suspension or Withdrawal, VA Form 22–0989.

OMB Control Number: 2900–0859.

Type of Review: Revision of a currently approved collection.

Abstract: The VA Form 22–0989 allows students to apply for restoration of entitlement for VA education benefits used at a school that closed, suspended, or had its approval to receive VA benefits withdrawn.

Affected Public: Individuals and Households.

Estimated Annual Burden: 659 hours.

Estimated Average Burden Time per Respondent: 15 minutes.

Frequency of Response: Once on occasion.

Estimated Number of Respondents: 2,634.

By direction of the Secretary.

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–03233 Filed 2–15–24; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

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Part II

Department of the Treasury

Financial Crimes Enforcement Network

31 CFR Chapter X

Anti-Money Laundering Regulations for Residential Real Estate Transfers;
Proposed Rule

DEPARTMENT OF THE TREASURY**Financial Crimes Enforcement Network****31 CFR Chapter X****RIN 1506–AB54****Anti-Money Laundering Regulations for Residential Real Estate Transfers****AGENCY:** Financial Crimes Enforcement Network (FinCEN), Treasury.**ACTION:** Notice of proposed rulemaking.

SUMMARY: FinCEN is issuing a proposed rule to require certain persons involved in real estate closings and settlements to submit reports and keep records on identified non-financed transfers of residential real property to specified legal entities and trusts on a nationwide basis. Transfers made directly to an individual would not be covered by this proposed rule. The proposed rule describes the circumstances in which a report must be filed, who must file a report, what information must be provided, and when a report is due. These reports are expected to assist the U.S. Department of the Treasury; Federal, State, and local law enforcement; and national security agencies in addressing illicit finance vulnerabilities in the U.S. residential real estate sector and to curtail the ability of illicit actors to anonymously launder illicit proceeds through the purchase of residential real property, which threatens U.S. economic and national security.

DATES: Written comments on this proposed rule must be submitted on or before April 16, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2024–0005 and RIN 1506–AB54.

- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2024–0005 and RIN 1506–AB54.

Please submit comments by one method only.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary**

The U.S. Department of the Treasury (Treasury) has long recognized the illicit finance risks posed by abuse of the U.S.

real estate market and of legal entities and trusts by criminals and corrupt officials to launder ill-gotten gains through transfers of residential real estate. The abuse of U.S. residential real estate markets threatens U.S. economic and national security and can disadvantage individuals and small businesses that seek to compete fairly in the U.S. economy. The proposed rule is designed to enhance transparency nationwide in the U.S. residential real estate market and to assist Treasury, law enforcement, and national security agencies in protecting U.S. economic and national security interests by requiring certain persons involved in real estate closings and settlements to file reports and maintain records related to identified non-financed transfers of residential real estate to specified legal entities and trusts on a nationwide basis, including information regarding beneficial owners of those entities and trusts.

Among the persons required by the Bank Secrecy Act (BSA) to maintain anti-money laundering (AML) programs are “persons involved in real estate closings and settlements.”¹ Yet, for many years, FinCEN has exempted such persons from comprehensive regulation under the BSA and has issued a series of time-limited and geographically focused “geographic targeting orders” (GTOs) to the real estate sector in lieu of more comprehensive regulation. Information received in response to FinCEN’s GTOs relating to non-financed transfers of residential real estate (Residential Real Estate GTOs) have demonstrated the need for increased transparency and further regulation of this sector. This notice of proposed rulemaking (NPRM) thus proposes a new reporting requirement for non-financed residential real estate transactions, consistent with the BSA’s longstanding directive to impose AML requirements on persons involved in real estate closings and settlements. At the same time, FinCEN has carefully considered the comments received in response to an advance notice of proposed rulemaking (ANPRM) on Anti-Money Laundering Regulations for Real Estate Transactions, and FinCEN appreciates the burdens that traditional AML program and SAR requirements may impose on persons involved in real estate transactions. This NPRM therefore proposes a streamlined reporting framework designed to minimize unnecessary burdens while also enhancing transparency. Although certain information collected under this proposed rule may also be available to

law enforcement, in some instances, through the new beneficial ownership reporting requirements imposed by the Corporate Transparency Act (CTA), the CTA’s reporting regime and this proposed rule serve different purposes.

In contrast to the beneficial ownership reporting requirements outlined in the CTA, this proposed rule is a tailored reporting requirement that would capture a particular class of activity that Treasury deems high-risk and that warrants reporting on a transaction-specific basis. More specifically, the proposed rule would require certain persons involved in residential real estate closings and settlements to file, and to maintain a record of, a streamlined version of a Suspicious Activity Report (SAR), referred to here as a “Real Estate Report.” The persons subject to these reporting and recordkeeping requirements would be deemed reporting persons for purposes of the proposed rule and would be determined through a “cascading” approach based on the function performed by the person in the real estate closing and settlement. The “cascade” is designed to minimize burdens on persons involved in real estate closings and settlements while avoiding gaps in reporting and incentives for evasion. To provide some flexibility in this cascade approach, real estate professionals would also have the option to designate a reporting person from among those in the cascade by agreement.

The information required to be reported in the Real Estate Report would identify the reporting person, the legal entity or trust to which the residential real property is transferred, the beneficial owners of that transferee entity or transferee trust, the person that transfers the residential real property, and the property being transferred, along with certain transactional information about the transfer. The reporting person would be required to file the Real Estate Report no later than 30 days after the date of closing. Because of the streamlined nature of these Real Estate Reports compared to traditional SARs, as well as the flexible “cascade” framework, persons subject to this reporting requirement would not need to maintain the types of AML programs otherwise required of financial institutions under the BSA.²

¹ 31 U.S.C. 5312(a)(2)(U).

² 31 U.S.C. 5318(h).

II. Background

A. Illicit Finance Risks in the U.S. Real Estate Sector

As Secretary of the Treasury (Secretary) Yellen noted at the 2023 Summit for Democracy, “[c]orrupt actors have for decades anonymously stashed their ill-gotten gains in real estate. Those looking to exploit our system have been able to—with anonymity—store illicit proceeds in an appreciating asset . . . Treasury is working to remove that anonymity[.]”³ The Secretary has made increasing transparency in the domestic and international financial system a national priority, noting that “illicit proceeds . . . equaling an estimated two percent of U.S. gross domestic product (GDP) flow through the U.S. financial system each year. Permitting illicit actors to benefit from the stability and security of the U.S. financial system weakens financial transparency, distorts markets, and hurts ordinary Americans.”⁴ Treasury’s Strategic Plan for 2022 to 2026 makes clear that one indicator of success in combatting illicit actors’ abuse of the U.S. financial system is achieving an “updated regulatory framework for real-estate [sic] to effectively cover cash transactions.”⁵

The United States’ stable real estate market and strong property rights protections make U.S. residential real estate attractive to illicit actors looking to launder the proceeds of crime and corruption. This is particularly the case for non-financed transfers that are currently outside the purview of the due diligence requirements imposed on regulated financial institutions pursuant to the BSA. For purposes of this rule, a non-financed transfer is any transfer that does not involve an extension of credit to the transferee secured by the transferred residential real property⁶ and extended by a financial institution that has both an obligation to maintain an AML program and an obligation to

report suspicious transactions. Money launderers exploit the absence of an obligation on any party to a non-financed transfer to conduct due diligence.

As a result, and as the Administration’s 2021 U.S. Strategy for Countering Corruption notes, the United States’ real estate market is a significant destination for the laundered proceeds of illicit activity. Treasury’s 2022 National Money Laundering Risk Assessment (2022 NMLRA) also reflects this. The 2022 NMLRA identifies a lack of transparency in non-financed real estate transfers in particular as a key weakness in the U.S. Anti-Money Laundering and Countering the Financing of Terrorism (AML/CFT) regulatory regime.⁷

International bodies, such as the Financial Action Task Force (FATF) and non-government organizations, have likewise noted the sector’s appeal for illicit actors intent on laundering funds.⁸ In particular, the FATF has recommended that the United States take appropriate action to address money laundering risks in relation to non-financed transfers of real estate.⁹ Furthermore, open-source investigative reports have demonstrated that criminal actors frequently employ legal entities, such as limited liability companies (LLCs), to launder money, including through real estate. In August 2021, Global Financial Integrity (GFI), a non-governmental organization, published a study estimating that at least \$2.3 billion had been laundered through the U.S. real estate market from 2015 to 2020 and the “use of anonymous shell companies and complex corporate structures continue[d] to be the number

one money laundering typology” involving real estate.¹⁰ Additionally, over 50 percent (30 of the 56 cases the study examined) involved politically exposed persons (PEPs), which the FATF has found “may be able to use their political influence for profit illegally [and] . . . thus may present a risk higher than other customers.”¹¹ GFI also highlighted that legal entities and trusts are frequently used to make such purchases, and that purchases are rarely made in the name of the PEP. For example, a 2020 forfeiture complaint filed by the Department of Justice (DOJ) alleged that a former president of a country in Africa and his spouse used funds derived from corruption to purchase U.S. residential properties worth millions of dollars via a trust.¹² Such crimes undermine the national security goals of the United States, one pillar of which is countering corruption.¹³ FinCEN’s own December 2022 analysis revealed that between March and October 2022—the eight months following the invasion of Ukraine—Russian oligarchs sent millions of dollars to their children to purchase residential real estate in the

¹⁰ Global Financial Integrity, “Acres of Money Laundering: Why U.S. Real Estate is a Kleptocrat’s Dream” (Aug. 2021), pp. 13–16, available at <https://gfin integrity.org/report/acres-of-money-laundering-why-u-s-real-estate-is-a-kleptocrats-dream/>. According to its website, GFI is “a Washington, DC-based think tank focused on illicit financial flows, corruption, illicit trade and money laundering.” See Global Financial Integrity, “About,” available at <https://gfin integrity.org/about/>.

¹¹ Financial Action Task Force, Guidance for a Risk Based Approach: Real Estate Sector (July 2022), pp. 29–30, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/RBA-Real-Estate-Sector.pdf.coredownload.pdf>; see e.g., U.S. Department of Justice, Press Release, Over \$1 billion in misappropriated 1MDB Funds Now Repatriated to Malaysia (Aug. 5, 2021), available at <https://www.justice.gov/opa/pr/over-1-billion-misappropriated-1mdb-funds-now-repatriated-malaysia>. The term “PEP” generally includes a current or former senior foreign political figure, their immediate family, and their close associates. See Federal Financial Institutions Examination Council, FFIEC BSA/AML Examination Manual, Politically Exposed Persons—Overview (v5 2015), p. 290; see also Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Financial Crimes Enforcement Network, National Credit Union Administration, and Office of the Comptroller of the Currency, Joint Statement on Bank Secrecy Act Due Diligence Requirements for Customers Who May Be Considered Politically Exposed Persons (Aug. 21, 2020), available at <https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20200821a1.pdf>.

¹² See Complaint for Forfeiture, *U.S. v. Real Property Located in Potomac, Maryland, Commonly Known as 9908 Bentcross Drive, Potomac, MD 20854* (D. Md. July 15, 2020) (Case No. 20–cv–02071).

¹³ The White House, National Security Strategy (Oct. 2022), p. 36, available at <https://www.whitehouse.gov/wp-content/uploads/2022/10/Biden-Harris-Administrations-National-Security-Strategy-10.2022.pdf>.

³ U.S. Department of the Treasury, Remarks by Secretary Janet L. Yellen on Anti-Corruption as a Cornerstone of a Fair, Accountable, and Democratic Economy at the Summit for Democracy (Mar. 28, 2023), available at <https://home.treasury.gov/news/press-releases/jy1371>.

⁴ *Id.*; U.S. Department of the Treasury, Strategic Plan 2022–2026 (2022), p. 23, available at <https://home.treasury.gov/system/files/266/Treasury-StrategicPlan-FY2022-2026.pdf>.

⁵ *Id.* at p. 24.

⁶ For the purposes of this proposed rule, “residential real property” means: (1) real property located in the United States containing a structure designed principally for occupancy by one to four families; (2) vacant or unimproved land located in the United States zoned, or for which a permit has been issued, for the construction of a structure designed principally for occupancy by one to four families; or (3) shares in a cooperative housing corporation.

⁷ The White House, United States Strategy for Countering Corruption (Dec. 2021), p. 22, available at <https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-on-Countering-Corruption.pdf>; U.S. Department of the Treasury, National Money Laundering Risk Assessment (Feb. 2022), p. 5, available at <https://home.treasury.gov/system/files/136/2022-National-Money-Laundering-Risk-Assessment.pdf>.

⁸ The FATF is a global standard-setter of anti-money laundering and counter terrorist financing guidelines. The FATF has noted that “[c]riminals gravitate towards sectors that apply or are believed to apply less comprehensive regulation and mitigation measures or where supervision is found to be lacking,” and that “[t]he purchase of real estate allows for the movement of large amounts of funds all at once in a single transaction as opposed to multiple transactions of smaller values.” See Financial Action Task Force, Guidance for a Risk Based Approach: Real Estate Sector (July 2022), p. 18, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/RBA-Real-Estate-Sector.pdf.coredownload.pdf>.

⁹ See Financial Action Task Force, United States Mutual Evaluation Report (Dec. 2016), p. 1, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/mer/MER-United-States-2016.pdf.coredownload.inline.pdf>.

United States, often via legal entities, demonstrating the appeal of residential real estate even to the potential targets of U.S. sanctions.¹⁴

As numerous public law enforcement actions illustrate, non-financed purchases of residential real estate by certain legal entities and trusts are acutely vulnerable to exploitation by illicit actors, due to a general lack of AML regulations covering or applicable to transfers conducted in this manner.¹⁵

¹⁴ See FinCEN, Financial Trend Analysis—Trends in Bank Secrecy Act Data: Financial Activity by Russian Oligarchs in 2022 (Dec. 2022).

¹⁵ See, e.g., *U.S. v. Delgado*, 653 F.3d 729 (8th Cir. 2011) (drug trafficking, money laundering); *U.S. v. Fernandez*, 559 F.3d 303 (5th Cir. 2009) (drug trafficking, money laundering); Complaint for Forfeiture, *U.S. v. All the Lot or Parcel of Land Located at 19 Duck Pond Lane Southampton, New York* 11968, Case No. 1:23-cv-01545 (S.D.N.Y. Feb. 24, 2023) (sanctions evasion); Indictment and Forfeiture, *U.S. v. Maikel Jose Moreno Perez*, Case No. 1:23-cr-20035-RNS (S.D. Fla. Jan. 26, 2023) (bribery, money laundering, conspiracy); Motion for Preliminary Order of Forfeiture and Preliminary Order of Forfeiture, *U.S. v. Colon*, Case No. 1:17-cr-47-SB (D. Del. Nov. 18, 2022) (drug trafficking, money laundering); *U.S. v. Andrii Derkach*, Cr. No. 22-432 (E.D.N.Y. Sept. 26, 2022) (sanctions evasion, money laundering, bank fraud); Doc. No. 10 at p. 1, *U.S. vs. Ralph Steinmann and Luis Fernando Vuiz*, Case No. 22-2-306-CR-Gayles/Torres (S.D. Fla. July 12, 2022) (bribery, money laundering); *U.S. v. Jimenez*, 2022 U.S. Dist. LEXIS 77685, 2022 WL 1261738 (S.D.N.Y. Apr. 28, 2022) (Case No. 1:18-cr-00879) (false claim fraud, wire fraud, money laundering, identity theft); Complaint for Forfeiture, *U.S. v. Real Property Located in Potomac, Maryland, Commonly Known as 9908 Bentcross Drive, Potomac, MD 20854*, Case No. 20-cv-02071 (D. Md. July 15, 2020) (public corruption, money laundering); Final Order of Forfeiture, *U.S. v. Raul Torres*, Case No. 1:19-cr-390 (N.D. Ohio Mar. 30, 2020) (operating an animal fighting venture, operating an unlicensed money services business, money laundering); *U.S. v. Bradley*, 2019 U.S. Dist. LEXIS 141157, 2019 WL 3934684 (M.D. Tenn. Aug. 20, 2019) (Case No. 3:15-cr-00037-2) (drug trafficking, money laundering); Indictment, *U.S. v. Patrick Ifediba, et al.*, Case No. 2:18-cr-00103-RDP-JEO, Doc. 1 (N.D. Ala. Mar. 29, 2018) (health care fraud); Redacted Indictment, *U.S. v. Paul Manafort*, Case 1:18-cr-00083-TSE (E.D. Va. Feb. 26, 2018) (money laundering, acting as an unregistered foreign agent); *U.S. v. Miller*, 295 F. Supp. 3d 690 (E.D. Va. 2018) (wire fraud); *U.S. v. Coffman*, 859 F. Supp. 2d 871 (E.D. Ky. 2012) (mail, wire, and securities fraud); *U.S. v. 10.10 Acres Located on Squires Rd.*, 386 F. Supp. 2d 613 (M.D.N.C. 2005) (drug trafficking); *Atty. Griev. Comm'n of Md. v. Blair*, 188 A.3d 1009 (Md. Ct. App. 2018) (money laundering drug trafficking proceeds); *State v. Harris*, 861 A.2d 165 (NJ Super. Ct. App. Div. 2004) (money laundering, theft); see also U.S. Department of Justice, Press Release, United States Reaches Settlement to Recover More Than \$700 Million in Assets Allegedly Traceable to Corruption Involving Malaysian Sovereign Wealth Fund (Oct. 30, 2019), available at <https://www.justice.gov/opa/pr/united-states-reaches-settlement-recover-more-700-million-assets-allegedly-traceable>; U.S. Department of Justice, Press Release, Acting Manhattan U.S. Attorney Announces \$5.9 Million Settlement of Civil Money Laundering And Forfeiture Claims Against Real Estate Corporations Alleged to Have Laundered Proceeds of Russian Tax Fraud (May 12, 2017), available at [https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-59-](https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-59-million-settlement-civil-money-laundering-and)

While many non-financed residential real estate transfers may involve no illicit funds, a substantial proportion of such non-financed transactions are conducted by persons also engaged in activity characterized by other financial institutions as suspicious, and reporting on such non-financed residential real estate transactions is of significant value to law enforcement. For example, the individuals and entities identified in Residential Real Estate GTO reports correlate with traditional SAR filings by financial institutions: FinCEN has found that approximately 42 percent of non-financed real estate transfers captured by the Residential Real Estate GTOs are conducted by individuals or legal entities on which a SAR has been filed. In other words, persons of potential interest to law enforcement due to their engagement in suspicious activity are also engaging in a type of transaction known to be used as a method of money-laundering: the non-financed purchase of residential real estate through a legal entity.

In addition to the law enforcement and national security concerns regarding abuse of the residential real estate sector, money laundering through residential real estate can distort real estate prices and potentially make it more difficult for legitimate buyers and sellers to participate in the market. In particular, the presence of illicit funds in the real estate sector can affect housing prices.¹⁶ Legitimate buyers are also adversely affected by illicit actors' preference to avoid financing, as sellers generally favor such "all-cash" offers due to the speed with which a sale can be closed.¹⁷

million-settlement-civil-money-laundering-and; U.S. Department of Justice, Press Release, Associate of Sanctioned Oligarch Indicted for Sanctions Evasion and Money Laundering: Fugitive Vladimir Vorontchenko Aided in Concealing Luxury Real Estate Owned by Viktor Vekselberg (Feb. 7, 2023), available at <https://www.justice.gov/usao-sdny/pr/associate-sanctioned-oligarch-indicted-sanctions-evasion-and-money-laundering>. Moreover, as the FATF noted in July 2022, "[d]isparities with rules surrounding legal structures across countries means property can often be acquired abroad by shell companies or trusts based in secrecy jurisdictions, exacerbating the risk of money laundering." International bodies, such as the FATF have found that "[s]uccessful AML/CFT supervision of the real estate sector must contend with the obfuscation of true ownership provided by legal entities or arrangements[.]" Financial Action Task Force, Guidance for a Risk Based Approach: Real Estate Sector (July 2022), p. 17, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/RBA-Real-Estate-Sector.pdf.coredownload.pdf>.

¹⁶ See, e.g., Richard Vanderford, "Fraudulent Covid Aid Drove Up U.S. House Prices, Report Says," *The Wall Street Journal* (June 22, 2023).

¹⁷ See The White House, United States Strategy for Countering Corruption (Dec. 2021), p. 7, available at [https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-](https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-for-Countering-Corruption.pdf)

Due to the illicit finance risks presented and the attendant economic burdens of market abuse, FinCEN's public efforts to counter money laundering in the real estate sector have focused on the use of legal entities by illicit actors to obfuscate ownership of residential real property.¹⁸ The reasoning behind this focus on legal entities is discussed extensively in FinCEN's December 2021 Anti-Money Laundering Regulations for Real Estate Transactions ANPRM (2021 ANPRM), which highlighted how, as evidenced by open source investigative articles, law enforcement actions, and feedback from FinCEN's Residential Real Estate GTOs program, individuals intent on laundering money through residential real estate frequently take advantage of the opacity of shell companies or other legal entity structures to mask true beneficial ownership of a property and their involvement in real estate transfers.¹⁹

B. FinCEN's Prior Regulation of the Real Estate Sector

1. Current Law

Enacted in 1970, the Currency and Foreign Transactions Reporting Act, generally referred to as the BSA, is designed to combat money laundering, the financing of terrorism, and other illicit financial activity.²⁰ The Secretary is authorized to administer the BSA and to require financial institutions to keep

on-Countering-Corruption.pdf; Financial Action Task Force, Guidance for a Risk Based Approach: Real Estate Sector (July 2022), p. 19, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/RBA-Real-Estate-Sector.pdf.coredownload.pdf>.

¹⁸ See, e.g., FinCEN, Press Release, FinCEN Renews and Expands Real Estate Geographic Targeting Orders (Apr. 21, 2023), available at <https://www.fincen.gov/news-releases/fincen-renews-and-expands-real-estate-geographic-targeting-orders-1> (announcing the renewal of an effort to combat illicit finance by collecting information on legal entity purchases of real estate); FinCEN, FIN-2017-A003, Advisory to Financial Institutions and Real Estate Firms and Professionals (Aug. 22, 2017), p. 2 (noting that high-value residential real estate markets are vulnerable to penetration by foreign and domestic criminal organizations and corrupt actors, especially those misusing otherwise legitimate LLCs or other legal entities to shield their identities).

¹⁹ 86 FR 69589 (Dec. 8, 2021).

²⁰ See 31 U.S.C. 5311. Certain parts of the Currency and Foreign Transactions Reporting Act, its amendments, and the other statutes relating to the subject matter of that Act, have come to be referred to as the BSA. The BSA is codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1960, and 31 U.S.C. 5311-5314 and 5316-5336, and includes notes thereto, with implementing regulations at 31 CFR Chapter X. The Anti-Money Laundering Act of 2020, Section 6003(1) (Definitions), defines the BSA as section 21 of the Federal Deposit Insurance Act (12 U.S.C. 1829b), Chapter 2 of Title I of Public Law 91-508 (12 U.S.C. 1951 *et seq.*), and 31 U.S.C. chapter 53, subchapter II.

records and file reports that “are highly useful in criminal, tax, or regulatory investigations or proceedings” or in the conduct of “intelligence or counterintelligence activities, including analysis, to protect against international terrorism.”²¹ The Secretary delegated the authority to implement, administer, and enforce compliance with the BSA and its implementing regulations to the Director of FinCEN.²²

The BSA requires each covered financial institution to establish an AML/CFT program, which must include, at a minimum, “(A) the development of internal policies, procedures, and controls; (B) the designation of a compliance officer; (C) an ongoing employee training program; and (D) an independent audit function to test programs.”²³ The BSA also authorizes the Secretary to require covered financial institutions to report any suspicious transaction relevant to a possible violation of law or regulation (a “suspicious activity report” or “SAR”).²⁴ Among the financial institutions subject to those requirements under the BSA are “persons involved in real estate closings and settlements.”²⁵

FinCEN’s regulations implementing the BSA require banks, non-bank residential mortgage lenders and originators (RMLOs), and housing-related Government Sponsored Enterprises (GSEs) to file SARs and establish AML/CFT programs.²⁶ However, FinCEN’s regulations exempt other persons involved in real estate closings and settlements from the requirement to establish AML/CFT programs, and the regulations do not impose a SAR filing requirement on such persons.²⁷

2. FinCEN’s Real Estate Exemption

In 2002, FinCEN temporarily exempted certain financial institutions, including “persons involved in real estate closings and settlements” and “loan and finance companies,” from the requirement to establish an AML/CFT program. FinCEN explained that it would “continue studying the money laundering risks posed by these institutions in order to develop appropriate AML program

requirements.”²⁸ That additional time was needed to consider the businesses that would be subject to such requirements, as well as the nature and scope of the AML/CFT risks associated with those businesses.²⁹ FinCEN also explained its concern that many of these financial institutions were sole proprietors or small businesses, and FinCEN intended to avoid imposing “unreasonable regulatory burdens with little or no corresponding anti-money laundering benefits.”³⁰

In 2003, FinCEN issued an ANPRM regarding the AML/CFT program requirement for “persons involved in real estate closings and settlements” (2003 ANPRM). The 2003 ANPRM solicited comments on the money laundering risks in real estate closings and settlements, how to define “persons involved in real estate closings and settlements,” whether any persons involved in real estate closings and settlements should be exempted from the AML/CFT program requirement, and how to structure the requirement in light of the size, location, and activities of persons in the real estate industry.³¹ FinCEN received 52 comments on the 2003 ANPRM from individuals, various institutions and associations of interested parties, law firms, state bar associations, an office within DOJ, and an office within the Internal Revenue Service (IRS).³² Many comments suggested that the threat of money laundering through real estate warranted appropriate regulation, but commenters disagreed over the specific businesses that should be covered. FinCEN did not propose regulations in response to these comments, and persons involved in real estate closings and settlements continue to be exempt from the AML/CFT program requirement.

3. FinCEN’s Targeted Actions in the Real Estate Sector

While maintaining the exemption for persons involved in real estate closings and settlements, FinCEN has taken targeted action to address certain vulnerabilities in the real estate sector. In a 2012 final rule, FinCEN eliminated an exemption for “loan and finance

companies,” and required such companies—defined as RMLOs—to file SARs and comply with AML/CFT program obligations.³³ In a 2014 final rule, FinCEN extended similar requirements to the housing-related GSEs—Fannie Mae, Freddie Mac, and the Federal Home Loan Banks.³⁴ In a 2020 final rule, FinCEN also imposed additional AML/CFT obligations on banks lacking a federal functional regulator, ensuring that such entities would be subject to requirements to have an AML/CFT program and meet Customer Identification Program (CIP) and Customer Due Diligence (CDD) requirements, including the verification of beneficial owners of legal entity accounts, in addition to their existing SAR obligations (which would include reporting on transactions involving suspicious real estate transactions).³⁵

To address non-financed transfers of residential real estate that do not involve a bank or other lender, FinCEN also began to issue Residential Real Estate GTOs in 2016.³⁶ The Residential Real Estate GTOs require title insurance companies to file reports and maintain records concerning non-financed purchases of residential real estate above a certain price threshold by certain legal entities in select metropolitan areas of the United States.

Information received in response to the Residential Real Estate GTOs has confirmed the money laundering risks involved in non-financed transfers of residential real estate and provided FinCEN and its law enforcement partners with additional data about that money laundering typology. The data obtained through the Residential Real Estate GTOs has connected non-financed residential real property purchases by certain legal entities with the true beneficial owners making the purchases, thereby decreasing the ability of criminals to hide their identities while laundering money through real estate. FinCEN regularly receives feedback from law enforcement

³³ 77 FR 8148 (Feb. 14, 2012) (codified at 31 CFR part 1029).

³⁴ 79 FR 10365 (Feb. 25, 2014) (codified at 31 CFR part 1030).

³⁵ 85 FR 57129 (Sept. 15, 2020) (codified at 31 CFR 1020.210).

³⁶ See 31 U.S.C. 5326; 31 CFR 1010.370; Treasury Order 180–01 (Jan. 14, 2020), available at <https://home.treasury.gov/about/general-information/orders-and-directives/treasury-order-180-01>. In general, a GTO is an order administered by FinCEN which for a finite period of time imposes additional recordkeeping or reporting requirements on domestic financial institutions or other businesses in a given geographic area, based on a finding that the additional requirements are necessary to carry out the purposes of, or to prevent evasion of, the BSA. The statutory maximum duration of a GTO is 180 days, though it may be renewed.

²¹ 31 U.S.C. 5311(1).

²² Treasury Order 180–01, Paragraph 3(a) (Jan. 14, 2020), available at <https://home.treasury.gov/about/general-information/orders-and-directives/treasury-order-180-01>.

²³ 31 U.S.C. 5318(h)(1)(A)–(D).

²⁴ 31 U.S.C. 5318(g).

²⁵ 31 U.S.C. 5312(a)(2)(U).

²⁶ 31 CFR parts 1020, 1029, 1030.

²⁷ 31 CFR 1010.205(b)(1)(v).

²⁸ 67 FR 21110, 21111 (Apr. 29, 2002).

²⁹ *Id.* FinCEN initially exempted persons involved in closings and settlements for six months, and then subsequently extended the temporary exemption indefinitely. *Id.*; 67 FR 67547, 67548 (Nov. 6, 2002).

³⁰ 67 FR 21110, 21112 (Apr. 29, 2002).

³¹ 68 FR 17569 (Apr. 10, 2003).

³² See FinCEN’s website to review comments submitted, available at <https://www.fincen.gov/comments-advance-notice-proposed-rule-anti-money-laundering-programs-persons-involved-real-estate>.

partners that they use the information to generate new investigative leads, identify new and related subjects in ongoing cases, and support prosecution and asset forfeiture efforts. Taking that input into account, FinCEN has renewed the time-limited Residential Real Estate GTOs multiple times and has expanded them to cover additional metropolitan areas and methods of payment, yielding additional insight into the risks in both the luxury and non-luxury residential real estate markets.³⁷ The information on real estate purchases thus enables investigators to connect real estate transactions with other suspicious financial activity. Although the Residential Real Estate GTOs have been effective, they were intended to be a temporary information collection measure that is limited in duration, not a permanent solution to a nationwide problem.³⁸ The proposed nationwide reporting framework for certain residential real estate transfers, if finalized, would replace the current Residential Real Estate GTOs.

4. The 2021 Real Estate ANPRM

On December 8, 2021, FinCEN published an ANPRM requesting comment on potential AML regulations for certain real estate professionals.³⁹ The 2021 ANPRM solicited public comment on whether and how to address money laundering vulnerabilities in the U.S. real estate market, including whether a transactional reporting requirement, triggered when a real estate purchase meets certain conditions, should be imposed on real estate professionals under the BSA. The 2021 ANPRM also solicited comment on whether, in lieu of a transactional reporting requirement, FinCEN should promulgate AML/CFT program requirements and SAR filing requirements for persons involved in real estate closings and settlements, similar to those that are in place for banks and other financial institutions. The 2021 ANPRM further sought comment concerning many aspects of real estate transfers, including: views on the scope of potential regulation of non-financed residential and commercial real estate transfers by legal entities and legal arrangements such as trusts; the sector's vulnerability to money laundering; differences in residential

and commercial real estate transfers; due diligence best practices present in the industry; and the costs of any potential regulations.

In response to the 2021 ANPRM, FinCEN received 151 public comments from a wide variety of stakeholders, including real estate industry associations, law firms and associations, non-governmental organizations, credit unions, Members of Congress, academics, and members of the public. Approximately 41 were unique comments and 110 were uniform statements submitted by members of the title insurance industry.

In general, commenters were split in their opinions on whether FinCEN should require transactional reports⁴⁰ or require persons involved in real estate closings and settlements to have full AML/CFT program obligations.⁴¹ One commenter wrote that if FinCEN were to apply new reporting measures, it should work with the IRS to amend IRS Form 1099-S to include buyer-side information, along with the seller-side information it already collects.⁴² Still other commenters suggested expanding the Residential Real Estate GTOs program to cover the entire nation either all at once or incrementally.⁴³ FinCEN has considered all the comments that it received in response to the 2021 ANPRM in drafting this proposed rule.

III. FinCEN's Proposed Approach to a Real Estate Reporting Requirement

A. Streamlined SAR Requirement

FinCEN has considered the extent to which non-financed residential real

estate transactions should be subject to the standard AML program and SAR-filing requirements that the BSA applies to other financial institutions. By subjecting financial institutions to those requirements and expressly including "persons involved in real estate closings and settlements" among the types of financial institutions specified in the statute, the BSA appears to indicate an expectation that such persons comply with the same AML/CFT rules currently applicable to other types of financial institutions. Although FinCEN originally issued an exemption in 2002 that relieved persons involved in real estate closings and settlements from that obligation, that exemption was intended to be only temporary while FinCEN continued to study money laundering risks in the real estate sector.⁴⁴

After many years of study and several targeted and temporary actions to enhance transparency in the real estate sector, FinCEN is of the view that the money laundering risks for non-financed residential real estate transactions warrant comprehensive AML/CFT regulations. As explained above, such transactions can be used to facilitate and obscure illicit activity. And, as several commenters on the ANPRM have urged, AML programs and SAR-filing obligations would provide highly useful information to law enforcement about those transactions. FinCEN recognizes, however, that the standard AML program and SAR-filing requirements may be especially burdensome to persons involved in real estate transactions, as many of them may be small businesses or individuals who cannot easily implement an AML program designed to identify and report suspicious activity. Such programs, which require financial institutions to make risk-based judgments about transactions and suspicious activity, may also be ineffective if small businesses and individuals in the real estate sector have difficulty implementing them.

For these reasons, FinCEN is proposing a streamlined reporting requirement that differs from the requirements typically imposed on other financial institutions. In particular, section 5318(g) of the BSA authorizes the Secretary to require financial institutions to report, via SARs, any "suspicious transactions relevant to a possible violation of law or regulation."⁴⁵ But the BSA affords the Secretary flexibility in implementing that requirement, and indeed directs the Secretary to consider "the means by or

³⁷ FinCEN found that money laundering risks existed at lower price thresholds, and thus the current Residential Real Estate GTOs set a \$300,000 threshold for all covered jurisdictions, except for the City and County of Baltimore, for which the threshold is \$50,000.

³⁸ See *supra* note 36.

³⁹ See 86 FR 69589 (Dec. 8, 2021).

⁴⁰ National Association of Realtors, ANPRM Comment (Feb. 18, 2022), pp. 1, 14, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0128>.

⁴¹ See Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 9, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), pp. 3–4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>; Louise Shelley and Ross Delston, ANPRM Comment (Feb. 21, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0151>.

⁴² American Escrow Association, ANPRM Comment (Feb. 18, 2022), pp. 13–17, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0124>.

⁴³ See Prosperus Title, ANPRM Comment (Feb. 18, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0125>; Marisa N. Bocci, ANPRM Comment (Feb. 21, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0150>; RESPRO, ANPRM Comment (Feb. 21, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0152>.

⁴⁴ See 67 FR 21110 (Apr. 29, 2002).

⁴⁵ 31 U.S.C. 5318(g)(1)(A).

form in which the Secretary shall receive such reporting,” including relevant “burdens,” “efficiency,” and “benefits.”⁴⁶ A new provision added to the BSA by section 6202 of the Anti-Money Laundering Act of 2020 (AML Act) further directs FinCEN to “establish streamlined . . . processes to, as appropriate, permit the filing of noncomplex categories of reports of suspicious activity.” In assessing whether streamlined filing is appropriate, FinCEN must determine, among other things, that such reports would “reduce burdens imposed on persons required to report[.]” while at the same time “not diminish[ing] the usefulness of the reporting to Federal law enforcement agencies, national security officials, and the intelligence community in combating financial crime, including the financing of terrorism[.]”⁴⁷

Based on that authority, FinCEN is proposing to streamline the SAR reporting requirement for purposes of this rule and to create a new form—the Real Estate Report—to reflect this streamlined approach. FinCEN believes that a streamlined reporting requirement, without an accompanying AML/CFT program, is appropriate, as the proposed rule would impose a requirement to report basic, standardized information about all relevant transactions, nationwide.

FinCEN believes the proposed streamlined reporting requirement would enhance the usefulness of BSA reporting to Federal law enforcement agencies, national security officials, and the intelligence community for combating financial crimes. The information collected would contain crucial details about a typology of real estate transfers that present acute illicit finance risks and for which there is broad consensus that regulation is needed—information that would not otherwise be routinely identified and reported in a traditional SAR.

FinCEN also believes that a streamlined filing requirement would reduce the potential burden on reporting persons. The filing

requirement would be triggered when the conditions set forth in the proposed rule are met, which FinCEN believes will reduce the overall burden for most filers, compared to those that would be required when implementing a traditional AML program. The streamlined filing requirement, unlike the requirements for filing a traditional SAR, would entail no risk-based judgment about when to file and no narrative assessment. Thus, similar to a Currency Transaction Report (CTR), Form 8300, or report filed under the Residential Real Estate GTOs, the proposed Real Estate Report would not require filers to make discretionary decisions.⁴⁸ Because of this, while FinCEN’s traditional SAR authority mandates that SARs be guided by a financial institution’s AML/CFT program designed to ensure that those discretionary decisions are made appropriately, FinCEN believes that an AML/CFT program is not necessary for reporting persons to accurately prepare and file useful reports under the proposed rule.⁴⁹ For this reason, the proposed rule would exempt persons involved in real estate closings and settlements from the BSA’s requirement to establish AML/CFT programs—effectively maintaining the current exemption for such persons under 31 U.S.C. 5318(h)(1), in light of the new reporting requirement.⁵⁰

The proposed rule would also exempt reporting persons from the confidentiality provisions that the BSA applies to suspicious activity reporting.⁵¹ These confidentiality provisions typically serve to ensure that banks and other such financial institutions do not alert SAR subjects to the fact that a SAR is being filed based on a suspicion with respect to the subject, potentially inducing a behavior change and reducing the utility of the SAR. However, as the triggering criteria for the filing of the proposed streamlined filing (a non-financed

transfer to certain legal entities and trusts) would be known by all parties to the transfer, including those whose information will be collected and reported to FinCEN, the same confidentiality considerations do not apply.⁵²

B. The Corporate Transparency Act

FinCEN notes that certain information collected under this proposed rule—most notably the beneficial ownership information of certain legal entities—will be collected and available to law enforcement in certain instances by virtue of the new beneficial ownership reporting requirements imposed by the CTA and implemented through the Beneficial Ownership Information Reporting Requirements Rule (BOI Reporting Rule).⁵³ However, the CTA’s reporting regime and this proposed rule would serve different purposes. This proposed rule is designed as a tailored reporting requirement that would capture a particular class of activity that Treasury deems high-risk—namely, non-financed residential real estate transfers to certain legal entities and trusts—and that, given the risk, warrants reporting on a transaction-specific basis. The resulting reports could readily alert law enforcement to the persons involved in a transfer of assets that carries significant illicit finance risk. Indeed, as with traditional SARs, reports under this proposed rule would require reporting on specific real estate transactions and allow Treasury and law enforcement to connect money laundering through real estate with other types of potentially illicit activities and to conduct broad money laundering trend analysis. In contrast, the BOI Reporting Rule requires companies to file reports about the beneficial ownership of certain legal entities; however, this information is unlikely to shed light on purchases of real estate by criminal actors or allow law enforcement to map out purchases of residential real estate by individual criminals and money launderers as well as their networks. Although some information about real estate purchases may in some cases be separately available through other sources such as state land registries (as discussed

⁴⁶ 31 U.S.C. 5318(g)(5)(B)(i)–(iii).

⁴⁷ See AML Act, section 6202 (*codified at* 31 U.S.C. 5318(g)(D)(i)(1)). Section 6102(c) of the AML Act also amended 31 U.S.C. 5318(a)(2) to give the Secretary the authority to “require a class of domestic financial institutions or nonfinancial trades or businesses to maintain appropriate procedures, including the collection and reporting of certain information as the Secretary of the Treasury may prescribe by regulation, to . . . guard against money laundering, the financing of terrorism, or other forms of illicit finance.” FinCEN believes this authority also provides an additional basis for the reporting requirement proposed in this NPRM.

⁴⁸ Under the BSA and its implementing regulations, “each financial institution other than a casino shall file a [CTR] of each deposit, withdrawal, exchange of currency or other payment or transfer, by, through, or to such financial institution which involves a transaction in currency of more than \$10,000[.]” 31 CFR 1010.311; see also 31 U.S.C. 5313. Under the BSA, relevant IRS statutes, and associated implementing regulations, “[a]ny [individual, trust, estate, partnership, association, company or corporation] who, in the course of a trade or business . . . receives currency in excess of \$10,000 in 1 transaction (or 2 or more related transactions) shall . . . [file a Form 8300] with respect to the receipt of currency.” 31 CFR 1010.330(a)(1)(i); see also 31 U.S.C. 5331; 26 U.S.C. 7701(a)(1).

⁴⁹ See 31 U.S.C. 5318(g)(5)(C).

⁵⁰ See 31 CFR 1010.205(b)(v).

⁵¹ See 31 U.S.C. 5318(g)(2).

⁵² 31 U.S.C. 5318(a)(7).

⁵³ The BOI Reporting Rule implements the CTA’s reporting provisions. In recognition of the fact that illicit actors frequently use corporate structures to obfuscate their identities and launder ill-gotten gains, the BOI Reporting Rule requires certain legal entities to file reports with FinCEN that identify their beneficial owners. See 87 FR 59498 (Sept. 30, 2022). Access by authorized recipients to BOI collected under the CTA are governed by other FinCEN regulations. See 88 FR 88732 (Dec. 22, 2023).

below), the inclusion of both beneficial ownership information and real estate transaction information in a single report as proposed in this NPRM will enable law enforcement to access information about potential criminal activity in a more timely and efficient manner.

In addition, the information to be reported under this proposed rule would differ from the information to be reported under the CTA in several ways. For instance, the proposed rule would require reporting of certain information about beneficial owners that is not required to be reported under the CTA reporting regime.⁵⁴ A discussion of the content of the proposed Real Estate Report is included in Section IV.E. Furthermore, reports filed pursuant to the BOI Reporting Rule—Beneficial Ownership Information Reports—and reports filed pursuant to this proposed rule—Real Estate Reports—would be housed in different databases with differing access privileges. The proposed Real Estate Reports would be stored electronically in the same database as traditional SAR and other BSA reports, in keeping with the nature, purposes, and use of those reports.

Nevertheless, although they serve different purposes, the proposed rule adopts or adapts certain definitions from the BOI Reporting Rule where appropriate. These definitions are discussed in more detail in Section IV.B.

C. Lack of Alternative Sources of Relevant Information

While other investigative methods and databases may be available to law enforcement seeking information on persons involved in non-financed transfers of residential real property, such sources of information are often incomplete, unreliable, and diffuse, resulting in a misalignment between these sources and the potential risks posed by the transfers.⁵⁵ Furthermore, the non-uniformity of the title transfer processes across states and the fact that the recording of title information is largely done at the local level complicates and hinders investigative efforts. An investigator could spend months or even years going through the electronic or physical property records

databases of the over 3,000 counties in the United States, only some of which have digitized their records. Furthermore, although certain data about non-financed transfer could be obtained through the Residential Real Estate GTOs, those GTOs currently cover only 68 cities and counties are currently covered by the Residential Real Estate GTOs. In order to verify how many non-financed purchases of residential real estate a known illicit actor has made, law enforcement may have to issue subpoenas to each jurisdiction and potentially travel in-person to many counties to find the relevant information. Law enforcement is also likely to experience difficulty in finding beneficial ownership information for non-financed transfers of residential real estate to legal entities or trusts not registered in the United States. This is particularly key as international buyers contributed approximately \$59 billion to the existing-home U.S. residential real estate market from April 2021 to March 2022 and 44 percent of international purchases were non-financed, compared to 24 percent for all existing-home buyers.⁵⁶

The disjointed nature of existing local databases also poses a significant obstacle to a common investigative methodology employed by law enforcement when it searches for perpetrators of money laundering and other criminal activity—namely, identifying networks of individuals that have potentially engaged in suspicious activity. A search of the proposed Real Estate Reports would be far more efficient than searching incomplete commercial databases or potentially visiting thousands of county-level deed offices. FinCEN assesses that law enforcement would benefit from access to information about transfers that reflect an identified money laundering typology in one central location managed and hosted by the U.S. government. Finally, existing commercial databases do not collect important information that is the focus of this rule, including funds transfer information.

⁵⁶ See National Association of Realtors, 2022 International Transactions in U.S. Residential Real Estate (July 2022), pp. 4–5, available at https://cdn.nar.realtor/sites/default/files/documents/2022-international-transactions-in-us-residential-real-estate-07-18-2022.pdf?_gl=1*3orrzx*_gcl_au*MTc4MTk3NTgzOS4xNjg3OTg1MTYy. The overall dollar value of international investment in residential real estate was comparatively low from 2021–2022 compared to the prior ten years due, in part, to investment and travel restrictions accompanying the COVID–19 pandemic. FinCEN believes this dollar value, in the absence of pandemic conditions, may therefore experience some mean reversion.

IV. Section-by-Section Analysis

The proposed rule would impose reporting and recordkeeping requirements related to certain transfers of residential real property (reportable transfers). The reporting and recordkeeping obligations would primarily apply to “reporting persons,” who are certain persons involved in real estate closings and settlements. Generally, the reporting person would be identified on the basis of their order in a “cascade” of specific functions performed by various persons involved in facilitating the closing or settlement of a real estate transaction. The proposed rule would also allow persons in the cascade to designate the reporting person amongst themselves.

The reporting person would be required to report information identifying the transferee entity or trust, the beneficial owners of the transferee entity or trust, and certain individuals signing documents on behalf of the transferee entity or transferee trust (signing individual), as well as information concerning the reporting person, the transferor, the real estate transferred, and certain payment information. The reporting person would be required to file a Real Estate Report with FinCEN and maintain a copy of that report, along with a certification by the transferee’s representative as to the identities of the beneficial owner(s) of the transferee, for a period of five years. If the persons involved in facilitating the closing or settlement enter into a designation agreement with regard to the reporting person, then the parties to the agreement would also be required to retain that agreement for a period of five years.⁵⁷

A. Residential Real Property in Reportable Transfers

1. Reportable Residential Real Property

The proposed rule is meant to broadly capture residential real property such as single-family houses, townhouses, condominiums, and cooperatives, as well as apartment buildings designed for one to four families. These properties would be captured even if there is also a commercial element to the property, such as a single-family residence that is located above a commercial enterprise. The proposed rule would also include certain types of land on which a residence is not yet built. The criteria for whether property falls within the parameters of the rule can be met in one of three ways: (1) it is real property that includes a structure

⁵⁴ For example, the CTA reporting regime will only indirectly require trusts to report their beneficial owners if an individual indirectly owns or controls a reporting company through a trust.

⁵⁵ See generally Sarah Mancini, Kate Lang, and Chi Wu, “Mismatched and Mistaken: How the Use of an Inaccurate Private Database Results in SSI Recipients Unjustly Losing Benefits,” National Consumer Law Center (Apr. 2021), available at <https://www.nclc.org/wp-content/uploads/2022/08/RptMismatchedFINAL041421.pdf>.

⁵⁷ See 31 CFR 1010.430(d).

designed principally for occupancy by one to four families; (2) it is land that is vacant or unimproved, and that is zoned, or for which a permit has been issued, for occupancy by one to four families; or (3) it is a share in a cooperative housing corporation. This definition modifies and expands the definition of “residential real property” used in the Residential Real Estate GTOs.

Although shares of a cooperative are generally treated under state law as personal property rather than real property, FinCEN believes that the money laundering risks for residential cooperatives are similar to those of condominiums and other residential real property. A cooperative is a corporation, and the owners of the cooperative are the corporation’s shareholders. Receiving ownership of shares in a cooperative therefore differs from receiving ownership of real property, as it does not include the filing of a deed specifying that ownership of a piece of real property has been transferred. However, the fundamental purpose of owning shares in a cooperative is to possess a piece of real property—generally a unit in an apartment owned by the cooperative. As the primary purpose for owning shares in a cooperative is to occupy real property, and because the market for cooperatives overlaps with the market for condominiums and other types of real property, FinCEN believes that it is appropriate to treat shares of a cooperative as residential real property for purposes of this rule. Without this treatment, money laundering risks may be unduly incentivized to shift investments to this segment of the real estate market.

The proposed rule also makes clear that reportable residential real property includes property located in the United States, which is defined in the BSA implementing regulations to mean any State, the District of Columbia, the Indian lands (as that term is defined in the Indian Gaming Regulatory Act), and territory or possession of the United States.⁵⁸ FinCEN believes this geographical scope is appropriate and that more limited coverage would likely push illicit activity into non-covered areas. Furthermore, a uniform national approach will provide consistency and predictability for businesses required to maintain records and make reports under this proposed rule.

2. Ownership Interests in Reportable Residential Real Property

For purposes of the proposed rule, a person may hold an ownership interest in residential real property if the person has rights to the property that are demonstrated through a deed or, for an interest in a cooperative housing corporation, through stock, shares, membership, a certificate, or other contractual agreement evidencing ownership.

Deeds are documents demonstrating title over property and recording changes in ownership and are effective when signed by the transferor and delivered to the transferee. They are generally publicly recorded, and although not all deeds are filed as such, the majority are, and there are benefits to doing so, such as preempting disputes over ownership and effecting the ability to sell the property.

The ownership interests of a cooperative housing corporation are not reflected on a deed and are instead typically demonstrated through stock or shares. The holder of each ownership interest has the right to dispose of that stock or share, the value of which primarily reflects the value of the residence attached to the interest.

B. Transferees in Reportable Transfers

1. Transferee Entities

The proposed regulation would require reporting only if a transferee of an ownership interest in residential real property is a transferee entity or a transferee trust, as those terms are defined. Such a transfer would be reportable even if one or more other transferees (*i.e.*, those that are neither a transferee entity nor transferee trust) also receive an ownership interest in the same property as part of the same transaction. Generally, the proposed rule provides that a “transferee entity” is any person other than a transferee trust or an individual. For example, a transferee entity may be a corporation, partnership, estate, association, or limited liability company. However, the definition of a “transferee entity” contains exceptions for certain highly regulated entities.⁵⁹

⁵⁹ For example, as discussed further below, individuals and trusts (outside of statutory trusts) are excepted from the definition of “transferee entity.” In addition, certain types of legal entities that are exempt from the requirement to report beneficial ownership information under the CTA are also excepted. Trusts are considered “transferee trusts” rather than “transferee entities” to ensure the proposed rule differentiates between legal entities and legal arrangements.

The proposed definition is informed by comments submitted in response to the 2021 ANPRM. In general, the 2021 ANPRM commenters recognized the money laundering risks presented by transfers of residential real estate to certain legal entities and supported coverage of them in any potential regulation.⁶⁰ Some commenters stated that only legal entities that are not covered by the CTA should be covered by any potential regulation of the real estate sector, as their beneficial ownership information will not be collected under the BOI Reporting Rule.⁶¹ However, as discussed below, FinCEN believes that this would leave a serious regulatory gap that would prevent the proposed rule from achieving its purpose of addressing illicit finance risk in the residential real estate sector. One commenter suggested that FinCEN use the definition of “legal entity” that appears in FinCEN’s 2020 CDD Rule.⁶²

a. Regulated Entities

Although this rule does not rely on the CTA for its legal authority, FinCEN is proposing to adopt many of the CTA’s exemptions for purposes of this proposed definition, insofar as the policy rationales for those exemptions align with the goals of this proposed rule. The exemptions that FinCEN proposes to adopt would apply to legal entities that FinCEN believes have sufficient AML/CFT compliance obligations in the real estate context, and which are already subject to more government supervision, or have disclosure requirements that obviate the need for inclusion in this proposed rule.

⁶⁰ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 10, 24, 30, 39, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; American Land Title Association, ANPRM Comment (Feb. 17, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0020>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), pp. 3, 5, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), pp. 2, 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), pp. 2–3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>.

⁶¹ See American Land Title Association, ANPRM Comment (Feb. 17, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0020>.

⁶² Financial & International Business Association, ANPRM Comment (Feb. 21, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0142>.

⁵⁸ 31 CFR 1010.100(hhh).

The exclusions in the proposed rule that align with the CTA's exemptions largely turn on whether the entity in question is supervised by a government agency, is a government agency, or has disclosure requirements that may diminish illicit finance risk in the context of residential real property.⁶³

Specifically, the proposed rule would exclude U.S. governmental authorities, securities reporting issuers, and certain banks, credit unions, depository institution holding companies, money service businesses, brokers or dealers in securities, securities exchange or clearing agencies, other Exchange Act registered entities, insurance companies, state-licensed insurance producers, Commodity Exchange Act registered entities, public utilities, financial market utilities, and registered investment companies, as well as any legal entity whose ownership interests are controlled or wholly owned, directly or indirectly, by any of the above.

For example, in the residential real estate context, FinCEN assesses that the illicit finance risk of non-financed transfers is adequately diminished when a business must register its securities with the Securities and Exchange Commission (SEC) under Section 12 of the Securities Exchange Act of 1934 or must file Forms 10-K or other supplementary and periodic information under section 15(d) of the Securities Exchange Act of 1934. Persons who beneficially own more than five percent of a covered class of equity securities for these businesses must publicly file with the SEC certain information relating to such beneficial ownership.⁶⁴ Persons who are a director or an officer or who beneficially own more than 10 percent of such registered equity security (insiders) also must publicly report their ownership and transactions.⁶⁵

b. Non-Profit Organizations

The definition of transferee entity in the proposed rule should be read to include non-profit organizations.⁶⁶

FinCEN and at least four major federal financial institution regulators (the Federal Reserve Board of Governors, the Federal Deposit Insurance Corporation, the National Credit Union Administration, and the Office of the Comptroller of the Currency) have made clear that the U.S. government does not view the charitable sector as a whole as presenting a uniform or unacceptably high risk of being used or exploited for money laundering, terrorist financing, or sanctions violations. The agencies have also recognized that the vast majority of charities and other non-profit organizations comply with the law and properly support charitable and humanitarian causes.⁶⁷ The FATF also has made clear that only a small subset of non-profits sending funds cross-border should be considered high risk as it relates to serving as potential vehicles of terrorist financing.⁶⁸

However, non-profit organizations (a subset of which are often referred to as charities), have proven vulnerable to abuse by certain illicit actors and have been implicated in illicit finance schemes, including fraud, money laundering, tax evasion, and terrorist financing.⁶⁹ FinCEN's consultations with law enforcement indicate that charities are routinely the subjects of

investigations involving fraud and money laundering, and a review of criminal cases involving illicit finance crimes and non-profit organizations shows that such organizations are vulnerable to exploitation by illicit actors. Indeed, charities purporting to support such causes as AIDS research, police and firefighters, disabled youth, childhood hunger, and veterans' issues have been investigated and prosecuted for fraud and money laundering.⁷⁰ Further, non-profit organizations have been used by corrupt governmental officials to extort money from individuals seeking zoning approvals and permits;⁷¹ manipulated to engage in bribery of corrupt foreign officials;⁷² and exploited to finance terrorism.⁷³

Illicit funds funneled through non-profit organizations are often invested in residential real estate. For instance, in July 2021, the 11th Circuit affirmed the conviction and forfeiture judgments involving multiple non-profit organizations in Florida.⁷⁴ The defendants that exploited the non-profits were convicted of conspiracy to commit wire fraud, operation of an illegal gambling business, conspiracy to commit money laundering, and money laundering.⁷⁵ The court found that funds laundered through the non-profits were used to purchase three residential real estate properties in Florida, which were subsequently forfeited.⁷⁶

One 2021 ANPRM commenter specifically stated that FinCEN should

⁶⁷ Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, FinCEN, National Credit Union Administration, and Office of the Comptroller of the Currency, Joint Fact Sheet on Bank Secrecy Act Due Diligence Requirements for Charities and Non-Profit Organizations (Nov. 19, 2020), available at https://www.fincen.gov/sites/default/files/shared/Charities%20Fact%20Sheet%202011_19_20.pdf.

⁶⁸ Financial Action Task Force, Risk of Terrorist Abuse of Non-Profit Organisations (June 2014), p. 8, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/reports/Risk-of-terrorist-abuse-in-non-profit-organisations.pdf.coredownload.pdf>.

⁶⁹ See U.S. Department of the Treasury, "Protecting Charitable Organizations," available at <https://home.treasury.gov/policy-issues/terrorism-and-illicit-finance/protecting-charitable-organizations> (noting that "terrorists have exploited the charitable sector to raise and move funds, provide logistical support, encourage terrorist recruitment, or otherwise support terrorist organizations and operations"); U.S. Department of Justice, Press Release, Charity Founders Sentenced to Prison for Using Non-Profit to Steal from Donors and Cheat on Their Taxes (Nov. 6, 2020), available at <https://www.justice.gov/usao-sdca/pr/charity-founders-sentenced-prison-using-non-profit-steal-donors-and-cheat-their-taxes>; see generally Organization for Economic Cooperation and Development, Report on Abuse of Charities for Money-Laundering and Tax Evasion (Feb. 2009), available at <https://www.oecd.org/tax/exchange-of-tax-information/42232037.pdf>; World Bank, Combating the Abuse of Non-Profit Organizations (June 2015), available at <https://elibrary.worldbank.org/doi/pdf/10.1596/978-0-8213-8547-0>; Financial Action Task Force, Combating the Terrorist Financing Abuse of Non-Profit Organisations (Nov. 2023), available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/BPP-Combating-TF-Abuse-NPO-R8.pdf.coredownload.inline.pdf>.

⁷⁰ See *U.S. v. Lyons*, 472 F.3d 1055, 1061–1065 (9th Cir. 2007); *Dhafir v. U.S.*, 2015 U.S. Dist. LEXIS 197346, 2015 WL 13727329 (N.D.N.Y. June 25, 2015).

⁷¹ See generally *U.S. v. Hairston*, 46 F.3d 361 (4th Cir. 1995).

⁷² See generally *U.S. v. Chi Ping Patrick Ho*, 984 F.3d 191 (2d Cir. 2020) (in which a Chinese think tank registered in Hong Kong and in the United States as a public charity exploited a charity in Uganda to engage in money laundering and bribery under the Foreign Corrupt Practices Act).

⁷³ See *Sotloff v. Qatar Charity*, 2023 U.S. Dist. LEXIS 93911, 2023 WL 3721683 (S.D. Fla. May 30, 2023) (financial support for Hamas, Al Qaeda, and ISIS); *In re Terrorist Attacks on September 11, 2001*, U.S. Dist. LEXIS 247199*, *344 (S.D.N.Y. Apr. 27, 2020) (financial support for Al Qaeda); *Strauss v. Credit Lyonnais, S.A.*, 925 F. Supp. 2d 414, 415 (E.D.N.Y. 2013) (financial support for Hamas); U.S. Department of the Treasury, Press Release, Treasury Targets Hizballah Finance Official and Shadow Bankers in Lebanon (May 11, 2021), available at <https://home.treasury.gov/news/press-releases/jy0170> (highlighting a non-profit providing funding for Hizballah).

⁷⁴ *U.S. v. Masino*, 2021 U.S. App. LEXIS 22615, 2021 WL 3235301 (11th Cir. July 30, 2021); *U.S. v. Masino*, 2019 U.S. Dist. LEXIS 34862, 2019 WL 1045179 (N.D. Fla. Mar. 5, 2019).

⁷⁵ *U.S. v. Masino*, 2021 U.S. App. LEXIS 22615, 2021 WL 3235301 (11th Cir. July 30, 2021).

⁷⁶ *U.S. v. Masino*, 2019 U.S. Dist. LEXIS 34862, 2019 WL 1045179 (N.D. Fla. Mar. 5, 2019), *aff'd* *U.S. v. Masino*, 2021 U.S. App. LEXIS 22615, 2021 WL 3235301 (11th Cir. July 30, 2021).

⁶³ See 31 U.S.C. 5336(a)(11)(B)(xxi).

⁶⁴ See 15 U.S.C. 78m(d)(1), (g)(1); 17 CFR 240.13d-1.

⁶⁵ See U.S. Securities and Exchange Commission, "Officers, Directors, and 10% Shareholders," available at <https://www.sec.gov/education/smallbusiness/goingpublic/officersanddirectors>.

⁶⁶ Under U.S. tax law, non-profit organizations include tax-exempt organizations: charitable organizations, churches and religious organizations, private foundations, and other non-profits such as civic leagues, social clubs, labor organizations, and business leagues, under Internal Revenue Code Section 501(c)(3), as well as political organizations subject to Section 527 to the Internal Revenue Code. See IRS, "Exempt Organization Types," available at <https://www.irs.gov/charities-non-profits/exempt-organization-types>.

cover purchases by non-profits.⁷⁷ Another commenter detailed the regulations that cover non-profits and advocated against covering them.⁷⁸ Having considered the circumstances and comments in totality, FinCEN believes that non-profit organizations are vulnerable to abuse by illicit actors seeking to launder illicit proceeds through residential real estate. Accordingly, they would be captured under the proposed definition of transferee entity.

c. Unregistered Pooled Investment Vehicles

Pooled investment vehicles (PIVs) that are not registered with the SEC may be transferee entities for purposes of the proposed rule. Broadly, PIVs can include investment companies registered with the SEC, such as mutual funds and exchange-traded funds, as well as unregistered investment companies, such as private real estate investment trusts, certain real estate funds, special purpose financing vehicles, and private funds (which are usually categorized by their sponsors according to the investment strategy they pursue, and include funds such as hedge funds, private equity funds, and venture capital funds).⁷⁹ Under the proposed rule, PIVs that are investment companies and are registered with the SEC would be exempt from the definition of a transferee entity. The difference between registered and unregistered PIVs turns in part on whether the PIV is or is not excluded from registration requirements as an

investment company under the Investment Company Act of 1940.⁸⁰ PIVs that meet these exclusion requirements, and are therefore not registered with the SEC, do not have disclosure and reporting requirements that govern similar but public PIVs, such as mutual funds or exchange-traded funds.

Furthermore, unregistered PIVs are not subject to comprehensive AML/CFT regulation and are therefore vulnerable to abuse by illicit actors. The risks they present may be significant—the private fund sector, for example, holds approximately \$20 trillion assets under management—a number that has more than doubled over the past decade and is comparable to the holdings of highly regulated U.S. banks.⁸¹ In recent years, private funds have been used by sanctioned persons, corrupt officials, tax evaders, and other criminal actors as a gateway to the U.S. financial system. This includes funds stolen from Malaysia's sovereign wealth fund, 1MDB;⁸² Venezuela's state-owned oil and natural gas company, PDVSA;⁸³ and funds from a large-scale cryptocurrency fraud scam.⁸⁴

Unregistered PIVs have also been used to hide criminal proceeds in real estate. In one particular example, a criminal actor had a substantial ownership interest in a private fund and used it to both obfuscate and provide a veneer of legitimacy to illicit funds to

make U.S. real estate purchases.⁸⁵ Illicit actors may also hold a minority, non-controlling interest in an unregistered PIV, resulting in the unregistered PIV channeling that investor's illicit funds into real estate, as unregistered PIVs are not generally required to establish the identities of investors or look into the investor's source of funds.⁸⁶

Outside of the real estate sector, the lack of comprehensive AML/CFT coverage for unregistered PIVs has posed major national security challenges, enabling U.S. adversaries to invest in, and thereby gain access to, sensitive and emerging U.S. technologies.⁸⁷ In fact, according to a 2018 Department of Defense report, unregistered PIVs such as private funds and special purpose vehicles have allowed jurisdictions whose interests compete with the United States to “access the crown jewels of U.S. innovation,” including in the realms of artificial intelligence, sensors, virtual reality, self-driving vehicles, robotics, microchips, and facial and other image recognition technologies, without such activity being reviewed by the Committee on Foreign Investment in the United States or other relevant government authority, where required.⁸⁸

⁷⁷ See The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>.

⁷⁸ See Kirton McConkie, ANPRM Comment (Feb. 7, 2022), pp. 1–8, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0017>.

⁷⁹ The term “pooled investment vehicle” has a particular definition in Rule 206(4)–8 under the Investment Advisers Act of 1940. See 17 CFR 275.206(4)–8. However, the term is used more broadly in this NPRM. For information on private funds, see U.S. Securities and Exchange Commission, “Private Fund Adviser Overview,” available at <https://www.sec.gov/divisions/investment/guidance/private-fund-adviser-resources>. Section 202(a)(29) of the Advisers Act defines the term “private fund” as an issuer that would be an investment company, as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3), but for section 3(c)(1) or 3(c)(7) of that Act. Section 3(c)(1) excludes a privately-offered issuer having fewer than a certain number of beneficial owners. Section 3(c)(7) excludes a privately-offered issuer the securities of which are owned exclusively by “qualified purchasers” (generally, persons and institutions owning a specific amount of investments). See U.S. Securities and Exchange Commission, “Investment Company Registration and Regulation Package,” available at https://www.sec.gov/investment/fast-answers/divisionsinvestmentinvcoreg121504#P84_14584.

⁸⁰ *Id.*

⁸¹ See U.S. Securities and Exchange Commission, “Private Fund Statistics,” available at <https://www.sec.gov/divisions/investment/private-fund-statistics>. This figure reflects the assets of private funds managed by registered investment advisers only. Form PF is filed by certain investment advisers registered with the SEC to report confidential information about the private funds they advise. Form PF is not filed by investment advisers that advise private funds but that are not registered with the SEC. Form PF provides the SEC and Financial Stability Oversight Council (FSOC) with important information about the basic operations and strategies of private funds and has helped establish a baseline picture of the private fund industry for assessing systemic risk.

⁸² Peter Grant, “1MDB probe may be good news for Park Lane Hotel Investors,” *The Wall Street Journal* (July 26, 2016), available at <https://www.wsj.com/articles/1mdb-probe-may-be-good-news-for-park-lane-hotel-investors-1469554543>.

⁸³ See generally Criminal Complaint, *U.S. v. Guruceaga*, Case No. 1:18-cr-20685 (S.D. Fla. July 23, 2018).

⁸⁴ U.S. Department of Justice, Press Release, Former Partner of Locke Lord LLP Convicted in Manhattan Federal Court Of Conspiracy To Commit Money Laundering And Bank Fraud In Connection with Scheme To Launder \$400 Million Of OneCoin Fraud Proceeds (Nov. 21, 2019), available at <https://www.justice.gov/usao-sdny/pr/former-partner-locke-lord-llp-convicted-manhattan-federal-court-conspiracy-commit-money#:~:text=SCOTT%2C%20a%20former%20equity%20partner,and%20operated%20for%20that%20purpose>.

⁸⁵ See, e.g., Peter Grant, “1MDB probe may be good news for Park Lane Hotel Investors,” *The Wall Street Journal* (July 6, 2016), available at <https://www.wsj.com/articles/1mdb-probe-may-be-good-news-for-park-lane-hotel-investors-1469554543>; Complaint, *U.S. v. “The Wolf of Wall Street” Motion Picture*, Case No. 2:16-cv-05362–DSF–PLA (C.D. Cal. 2016); Will Parker, “Meet the secretive Kazakh company backing the Upper West Side’s latest skyscraper,” *The Real Deal: Real Estate News* (Apr. 14, 2018), available at <https://therealdeal.com/new-york/2018/04/13/meet-the-secretive-kazakh-company-backing-the-upper-west-sides-latest-skyscraper/>; Miranda Patrucic, Vlad Lavrov, and Ilya Lozovsky, “Kazakhstan’s Secret Billionaires,” *OCCRP* (Nov. 5, 2017), available at <https://www.occrp.org/en/paradisepapers/kazakhstans-secret-billionaires>.

⁸⁶ See, e.g., U.S. Department of Justice, Press Release, Acting Manhattan U.S. Attorney Announces Settlement of Civil Forfeiture Claims Against Over \$50 Million Laundered Through Black Market Peso Exchange (Nov. 12, 2020), available at <https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-settlement-civil-forfeiture-claims-against-over>.

⁸⁷ Cory Bennett and Bryan Bender, “How China acquires ‘The Crown Jewels’ of U.S. technology,” *Politico* (May 22, 2018), available at <https://www.politico.com/story/2018/05/22/china-us-tech-companies-cfius-572413>.

⁸⁸ Michael Brown and Pavneet Singh, “China’s Technology Transfer Strategy: How Chinese Investments in Emerging Technology Enable A Strategic Competitor to Access the Crown Jewels of U.S. Innovation,” Defense Innovation Unit Experimental (Jan. 2018), available at <https://nationalsecurity.gmu.edu/wp-content/uploads/2020/02/DIUX-China-Tech-Transfer-Study-Selected-Readings.pdf>; Paul Mozur and Jane Perlez, “China Tech investment flying under the radar, Pentagon warns,” *The New York Times* (Apr. 7, 2017).

FinCEN therefore believes that unregistered PIVs generally present sufficient illicit finance risk to warrant inclusion in the definition of a transferee entity. These unregistered PIV may include entities such as private funds,⁸⁹ certain market intermediaries,⁹⁰ certain companies that primarily engage in the business of acquiring mortgages,⁹¹ certain funds maintained by charitable organizations,⁹² and certain church plans.⁹³

d. Large Operating Companies

The proposed definition would capture certain legal entities that are known as “large operating companies” in the CTA and BOI Reporting Rule context. Within that framework, a large operating company is an entity that: “employs more than 20 employees on a full-time basis in the United States;” “filed in the previous year Federal income tax returns in the United States demonstrating more than \$5,000,000 in gross receipts or sales in the aggregate;” and “has an operating presence at a physical office within the United States[.]”⁹⁴ When explaining why this exemption was added to the CTA, Senator Sherrod Brown noted:

The justification for the exemption of entities that have both physical operations and at least 20 employees in the United States is that those entities’ physical U.S. presence will make it easy for U.S. law enforcement to discover those entities’ true owners. Like other exemptions in the bill, this exemption should be narrowly construed to exclude entities that do not have an easily located physical presence in the United States, do not have multiple employees physically present on an ongoing basis in the United States, or use strategies that make it difficult for U.S. law enforcement to contact their workforce or discover the names of their beneficial owners.⁹⁵

⁸⁹ Private funds often are excluded from the definition of “investment company” under 15 U.S.C. 80a–3(c)(1) and/or 15 U.S.C. 80a–3(c)(7).

⁹⁰ Certain market intermediaries are excluded from the definition of “investment company” under 15 U.S.C. 80a–3(c)(2).

⁹¹ Certain investment vehicles that are primarily engaged in “purchasing or otherwise acquiring mortgages and other liens on and interests in real estate” are excluded from the definition of “investment company” under 15 U.S.C. 80a–3(c)(5)(C).

⁹² Certain investment vehicles maintained by certain charitable organizations are excluded from the definition of “investment company” under 15 U.S.C. 80a–3(c)(10).

⁹³ Certain church plans are excluded from the definition of “investment company” under 15 U.S.C. 80a–3(c)(14).

⁹⁴ 31 U.S.C. 5336(a)(11)(B)(xxi).

⁹⁵ Senator Sherrod Brown, “National Defense Authorization Act,” Congressional Record 166: 208, p. S7311 (Dec. 9, 2020), available at <https://www.congress.gov/116/crec/2020/12/09/CREC-2020-12-09-pt1-PgS7296.pdf>.

Senator Brown cautioned however, that “[t]his exemption should be subject to continuous, careful review by Treasury . . . to detect and prevent its misuse.”⁹⁶

One of the primary purposes of the proposed rule is to identify transferee entities that engage in non-financed residential real estate transfers. While it may be easier for law enforcement to identify beneficial owners behind large operating companies in comparison to shell companies, the very fact that a legal entity has engaged in activity that FinCEN has identified as presenting an illicit finance risk—the use of identity obfuscating vehicles in a non-financed residential real estate transfer—is valuable information for law enforcement, both to support individual investigations and to allow for aggregated analysis of money laundering in the U.S. real estate sector.

However, certain large operating companies may fall within other exclusions provided for in the proposed rule. For example, a company required to register its securities with the SEC under section 12 of the Securities Exchange Act of 1934 would be excluded.

2. Transferee Trusts

The proposed rule defines “transferee trust” as any legal arrangement created when a person (generally known as a settlor or grantor) places assets under the control of a trustee for the benefit of one or more persons (each generally known as a beneficiary) or for a specified purpose, as well as any legal arrangement similar in structure or function to the above, whether formed under the laws of the United States or a foreign jurisdiction. The proposed rule further notes that a trust is deemed to be the transferee trust regardless of whether residential real property is titled in the name of the trust itself or in the name of the trustee in their capacity as the trustee of the trust. However, the proposed rule excludes trusts that are securities reporting issuers, which includes companies that must register securities with the SEC and become subject to periodic reporting and disclosure requirements. FinCEN considers these trusts to be more tightly supervised and, because they are required to make certain public disclosures, they present a lower illicit finance risk. For similar reasons, trusts that have a trustee that is a securities reporting issuer are not covered by the proposed rule. Furthermore, the proposed rule excludes statutory trusts from being transferee trusts; instead, a

statutory trust could be considered to be a transferee entity, unless one of the exemptions to the definition of “transferee entity” applies.

Multiple 2021 ANPRM commenters highlighted the use of trusts to facilitate exploitation of the real estate market for the purpose of laundering money, were largely supportive of including them in any regulation, and suggested that transfers to trusts be covered, particularly since the CTA did not explicitly provide for reporting of beneficial ownership information from trusts.⁹⁷ Other commenters recognized that trusts can present illicit finance risks but were only supportive of covering certain types.⁹⁸ As discussed in detail above, FinCEN believes that non-financed residential real estate transfers to trusts present a high risk for money laundering. The reporting of all non-financed transfers of residential real estate in which the transferee is a trust would provide data relevant to a possible violation of law or regulation.

3. Beneficial Owners of Transferee Entities and Transferee Trusts

The proposed Real Estate Report would collect information about the beneficial owners of transferee entities and transferee trusts. Where possible, FinCEN has aligned the proposed rule’s definitions of beneficial ownership with those contained in the CTA and its implementing regulations.

a. Determining the Beneficial Owners of Transferee Entities

Consistent with the CTA, the proposed rule provides that a beneficial owner of a transferee entity is “any

⁹⁷ See, Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 3, 30, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), pp. 3, 8, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; American College of Trust and Estate Counsel, ANPRM Comment (Feb. 4, 2022), pp. 1–22, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0013>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>.

⁹⁸ See American College of Trust and Estate Counsel, ANPRM Comment (Feb. 4, 2022), pp. 1–22, available at <https://www.regulations.gov/docket/FINCEN-2021-0007/comments?filter=ACTEC>; National Association of Realtors, ANPRM Comment (Feb. 18, 2022), p. 13, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0128>.

⁹⁶ *Id.*

individual who, directly or indirectly, either exercises substantial control over the transferee entity or owns or controls at least 25 percent of the ownership interests of the transferee entity.” However, as the owners or directors of tax-exempt organizations do not hold a direct ownership stake in the organization, the reportable beneficial owners would be limited only to the individuals who exercise substantial control.

Comments on the 2021 ANPRM were generally supportive of using the CTA’s definition of the beneficial owner in any potential regulation. However, one commenter suggested FinCEN use the definition of beneficial owner set out in the Residential Real Estate GTOs.

FinCEN considered that definition as well as other definitions for beneficial ownership for transferee entities. However, FinCEN believes that the BOI Reporting Rule’s definition would be best suited to capture potentially obfuscated ownership of residential real property in high-risk non-financed transfers, particularly since it will always result in the identification of at least one beneficial owner via the “substantial control” component of the definition, even if no individual meets the 25 percent “ownership interests” threshold. In addition, the use of consistent definitions of beneficial ownership across regulations would reduce the potential for confusion.

b. Determining the Beneficial Owners of Transferee Trusts

The proposed rule would collect information about the beneficial owners of trusts, defined as any individual who, at the time of the real estate transfer to the trust: (1) is a trustee; (2) otherwise has authority to dispose of transferee trust assets, such as may be the case with a trust protector;⁹⁹ (3) is a beneficiary who is the sole permissible recipient of income and principal from the transferee trust or who has the right to demand a distribution of, or to withdraw, substantially all of the assets of the transferee trust; (4) is a grantor or settlor of a revocable transferee trust; or

(5) is the beneficial owner of a legal entity or trust that holds one of the positions described in (1)–(4), taking into account the exceptions that apply to transferee entities and transferee trusts.

This proposed definition leverages the BOI Reporting Rule’s approach to ascertaining the beneficial owners of a trust. Although the BOI Reporting Rule does not require reporting of beneficial ownership information by most trusts, as most trusts are not “reporting companies” for purposes of the CTA, the rule does require certain information to be reported about the beneficial owners of trusts when an individual is considered to own or control a reporting company through a trust. In line with that approach, each of the defined beneficial owners of a transferee trust has either ownership or control over trust assets, including over any real property transferred to the trust. For example, an individual who is the sole permissible recipient of both income and principal from the trust, or has the right to demand a distribution of, or withdraw, substantially all of the assets from the trust, has an ownership or controlling interest in the assets held in trust. Other individuals with authority to dispose of trust assets, such as trustees and grantors or settlors that have retained the right to revoke the trust, will be considered as controlling the assets held in trust. In the case of legal entities or trusts with ownership or control of trust assets, the beneficial owners of those legal entities or trusts also would be beneficial owners of the trust.

c. Beneficial Ownership as a Transactional Reporting Requirement

The proposed rule would not require reporting persons to report changes to beneficial ownership of a transferee entity or transferee trust on an ongoing basis. The proposed rule is concerned only with real estate transfers, and it is not within the scope or intention of these regulations to require reporting persons to conduct ongoing monitoring of ownership of residential real property. While at least one 2021 ANPRM commenter supported the introduction of ongoing monitoring for change of ownership, most commenters did not address this issue. FinCEN assesses that it would likely represent a large and impractical burden to place an obligation on reporting persons that would require them to investigate changes to beneficial ownership of residential real estate that continues to be owned by a client transferee entity or trust, or to require transferee entities or transferee trusts to report changes in

beneficial ownership to a real estate professional involved in their transfer of residential real property after the transfer has been concluded.

C. Reportable Transfers

The proposed rule would define a reportable transfer as a transfer of any ownership interest in residential real property to a transferee entity or transferee trust, with certain exceptions. These proposed exceptions are meant to reflect FinCEN’s intent to capture only higher risk transfers and therefore the definition exempts most financed transfers, as well as certain types of other low-risk transfers. Under the proposed rule, transfers would be reportable irrespective of the value of the property or the dollar value of the transaction; there is no dollar threshold for a reportable transfer. As such, gifts and other similar transfers of property may be reportable. Importantly, transfers would only be reportable if a reporting person is involved in the transfer and if the transferee is either a legal entity or trust. Transfers between individuals would not be reportable.

1. Exception for Financed Transfers

First, certain financed transfers would be excepted. Specifically, the exception would apply to transfers involving an extension of credit to the transferee, but only if the credit is secured by the transferred residential real property and is extended by a financial institution that has both an obligation to maintain an AML program and a requirement to file SARs. Transfers financed by a private lender or the seller, neither of which are likely to have AML/CFT compliance programs and SAR filing obligations, would not fall within this exception. The purpose of the exception is to avoid duplication of required due diligence, as banks and other financial institutions subject to AML/CFT program requirements and SAR filing obligations must already extend them to any mortgages offered in a financed residential real estate transfer. Unlike in the non-financed space, these due diligence obligations of covered financial institutions mitigate the risks of money laundering through real estate for financed transactions and lead to reporting on suspicious transactions.

Some commenters on the 2021 ANPRM highlighted that non-financed purchases make up a significant portion of the residential real estate market.¹⁰⁰

⁹⁹ A trust protector is a person given power within the trust to take certain types of significant actions, such as the right to oversee the trustee’s decisions, to remove the trustee, or to amend or terminate the trust. See section 808 of the Uniform Trust Code (2003), available at <https://www.uniformlaws.org/viewdocument/committee-archive-76?CommunityKey=193ff839-7955-4846-8f3c-ce74ac23938d&tab=librarydocuments>; Andrew T. Huber, “Trust Protectors: The Role Continues to Evolve,” American Bar Association (Jan.–Feb. 2017), available at https://www.americanbar.org/groups/real_property_trust_estate/publications/probate-property-magazine/2017/january_february_2017/2017_aba_rpte_pp_v31_1_article_huber_trust_protectors/.

¹⁰⁰ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), p. 15, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.transparency.org/en/aml-cft>.

Most commenters who addressed the issue were supportive of FinCEN covering non-financed transfers.¹⁰¹ Some explicitly stated that only non-financed transfers should be covered, but two comments stated that FinCEN should cover both non-financed and financed transfers.¹⁰² Two commenters were not supportive of covering non-financed transactions, either because they believe real estate professionals are already reporting on potential financial crimes through other FinCEN forms, such as the Form 8300, or because they believe most settlement agents already force funds through financial institutions that have traditional AML/CFT program requirements.¹⁰³ However, FinCEN believes that further regulation is needed and its experience with the Residential Real Estate GTOs program has shown that existing reporting through Form 8300s and the minimal involvement of financial institutions subject to AML/CFT program requirements are not sufficient to obviate the illicit finance threat posed by non-financed transfers of residential real property.

2. Exceptions for Low-Risk Transfers

Exceptions also would exist for transfers that are the result of a grant, transfer, or revocation of an easement; transfers that occur as a result of the death of an owner of the residential real property; transfers that are the result of divorce or dissolution of marriage; or transfers to a bankruptcy estate. FinCEN views easements, which involve rights to use land for a specified purpose, as presenting little illicit finance risk. Transfers incidental to death, divorce, or bankruptcy are governed by

preexisting legal documents, such as wills, or generally involve the court system through probate, divorce, or bankruptcy proceedings. FinCEN believes these circumstances present a relatively low risk for purposes of laundering money.

3. No Exceptions Based on the Property's Value or Purchase Price

Residential real properties with a wide range of values are used by illicit actors to launder money, including residential real properties transferred for no consideration.¹⁰⁴ Criminal networks interested in cleaning funds do not exclusively invest in luxury or high-value property, but also launder money through low-value real estate. FinCEN believes that any dollar threshold would enable money launderers to structure payments to avoid reporting requirements. Accordingly, the proposed rule does not provide exceptions for transfers above or below a set dollar value. Furthermore, it is meant to capture both sales and non-sale transfers, such as gifts and transfers to trusts. The transfer of residential real property to a trust by the settlor or grantor may therefore be reportable, although FinCEN expects that such reporting will be significantly limited by the exception for transfers of financed residential real property and by the exception for transfers occurring as a result of death. The latter, in particular, would exempt transfers by an executor of the grantor or settlor's property to a testamentary trust.

FinCEN believes that the inclusion of low dollar value transfers in the proposed rule is unlikely to significantly increase the burden on potential reporting persons versus a scenario in which a dollar threshold is imposed. For example, according to the U.S. Census Bureau, residences costing less than \$125,000 accounted for less than 0.5 percent of all new residences sold in 2022, and residences costing less than \$300,000 accounted for 7 percent of all new residences sold in 2022.¹⁰⁵ The American Land Title Association (ALTA) has indicated to FinCEN that a uniform reporting threshold, regardless of what the threshold is, would decrease compliance burdens for industry compared to thresholds that vary across jurisdictions. With respect to non-sale

transfers made for no consideration, such as transfers made to a trust, FinCEN notes that the proposed rule provides the previously discussed exception for transfers that most often involve no consideration, such as those that occur due to death or divorce, which substantially narrows the scope of coverage. However, FinCEN welcomes comments on the potential burdens related to the reporting of non-sale transfers.

4. No Application to Transfers Without a Reporting Person

FinCEN believes that the proposed rule would capture the majority of sale and non-sale transfers of residential real estate. However, transfers that do not involve a typical real estate-related professional as reflected in the cascade of potential reporting persons would not be captured.

5. No Application to Transfers to Natural Persons

Transfers made directly to individuals would not be reportable under this regulation. Therefore, if the transferred property's title is in the name of one or more individuals, with no ownership interests held by a transferee entity or a transferee trust, the transfer would not be reportable under the rule.

Some 2021 ANPRM commenters recognized that non-financed transfers of residential real estate to individuals present money laundering risk and supported their coverage by any potential regulation.¹⁰⁶ Other commenters, however, stated that the burden of covering natural person purchases would be too large for the industry to bear and expressed privacy concerns.¹⁰⁷

All non-financed transfers of residential real estate are less regulated than financed transfers and are inherently more vulnerable to money

www.regulations.gov/comment/FINCEN-2021-0007-0115.

¹⁰¹ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), p. 15, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; League of Southeastern Credit Unions & Affiliates, ANPRM Comment (Feb. 7, 2022), pp. 1–4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0011>; Illinois Credit Union League, ANPRM Comment (Feb. 21, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0137>.

¹⁰² See Louise Shelley and Ross Delston, ANPRM Comment (Feb. 21, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0151>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>.

¹⁰³ See Morgan, Lewis, & Bockius, ANPRM Comment (Feb. 18, 2022), pp. 2–3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0123>; Prosperus Title, ANPRM Comment (Feb. 18, 2022), 1–2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0125>.

¹⁰⁴ For example, whereas the Residential Real Estate GTOs utilize a \$300,000 threshold for most covered jurisdictions, a \$50,000 threshold applies for the City and County of Baltimore to take into account local money laundering trends.

¹⁰⁵ U.S. Census Bureau, “Table Q1. New Houses Sold by Sales Price: United States,” available at https://www.census.gov/construction/nrs/pdf/quarterly_sales.pdf.

¹⁰⁶ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), p. 24, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), pp. 2–3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>.

¹⁰⁷ See National Federation of Independent Business, ANPRM Comment (Dec. 22, 2021), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0007>; American Land Title Association, ANPRM Comment (Feb. 17, 2022), p. 2–5, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0020>.

laundering. However, FinCEN has not yet conducted a review of residential real estate purchases by natural persons sufficient to conclude that those transactions present a high risk for money laundering. To be sure, illicit actors often use natural person nominees or straw purchasers—such as a spouse, relative, or employee—to acquire real estate while obscuring beneficial ownership.¹⁰⁸ Such nominees or straw purchasers are unlikely to disclose that they are receiving ownership of real estate on behalf of the illicit actor. Requiring the reporting of information about transfers to individuals would significantly increase the number of reports filed and significantly increase burden on industry. Although the BSA would provide privacy protections for reports filed under the proposed rule, for the reasons stated above, FinCEN is not proposing to cover residential real estate purchases by natural persons at this time.

D. Reporting Persons

The proposed rule would impose a filing and recordkeeping obligation on certain persons involved in real estate closings and settlements. The proposed rule would designate only one reporting person for any given reportable transfer. The reporting person would be identified in one of two ways: by way of a cascading reporting order or by way of a written agreement between the real estate professionals described in the cascading reporting order.

1. The Reporting Cascade

Through the cascade, a real estate professional would be a reporting person required to file a report and keep records for a given transfer if the person performs a function described in the cascade and no other person performs a function described higher in the cascade. For example, if no person is involved in the transfer as described in the first tier of potential reporting persons, the reporting obligation would fall to the person involved in the transfer as described in the second tier of potential reporting persons, if any, and so on. The cascade includes only persons engaged as a business in the provision of real estate closing and settlement services within the United States.

For any reportable transfer, a potential reporting person would need to determine whether there is another

potential reporting person involved in the transfer who sits higher in the cascade. Although potential reporting persons will likely communicate with each other regarding the need to file a report, there would be no requirement to verify that any other potential reporting person in fact filed it.

The proposed cascade is as follows:¹⁰⁹

First, *real estate professionals providing certain settlement services in the settlement process*—In the first instance, the reporting obligation would rest with real estate professionals providing certain settlement services at the termination of the settlement process. Specifically, the cascade first designates as a reporting person the person listed as the closing or settlement agent on a settlement (or closing) statement, which is common to the vast majority of residential real property transfers. This ensures that a potential reporting person familiar with the intricacies of the transfer, including transactional information and details about the parties involved, will be the most frequent reporting person. This, in turn, will ensure that the reports are more accurate and useful to law enforcement and will lessen the burden on reporting persons. In the event that no person is directly identified as a closing or settlement agent on the statement, the reporting obligation would fall on the person that prepared the closing or settlement statement. If no person prepared a closing or settlement statement, the reporting obligation falls to the person that files the deed or other instrument that transfers ownership of the residential real property.

Second, *the person that underwrites an owner's title insurance policy for the transferee*—If no person executes the specific settlement functions in the first tier of the cascade, the reporting obligation would then fall upon the person that underwrites the title insurance policy associated with the real property transfer. Such policies are typically underwritten by large title insurance companies that issue policies providing indemnity in the event the title of the transferred property is later determined to have a defect or

encumbrance.¹¹⁰ Title insurance companies have been the reporting persons for the Residential Real Estate GTOs since 2016 and have demonstrated the ability to gather information and file reports containing information similar to that which would be collected under the proposed rule. Given that the underwriting function is further removed from the termination of the settlement process than the settlement services described in the first tier of the cascade, and so further removed from information to be collected, FinCEN assesses that persons underwriting such policies should be second line reporting persons. Title insurance agents may serve as settlement agents and if serving such a first-tier function, would have easier access to the necessary information in that capacity.

Third, *the person that disburses the greatest amount of funds in connection with the reportable transfer*—In the event that no person executes the specific settlement functions in the first tier of the cascade, and no person underwrites a title insurance policy, the third tier of the cascade would require reporting by the person that disburses the greatest amount of funds in connection with residential real property transfer. The proposed rule notes that such disbursement may be in any form, including from an escrow account (which is frequently used to settle real estate transfers), from a trust account, or from a lawyer's trust account. Such reporting persons will have visibility into funds transfer information associated with the residential real property transfer and FinCEN believes that, by virtue of this, they should be able to obtain the information this proposed rule would collect with relatively little burden. However, this tier of the cascade would only cover persons involved in real estate settlements and closings who are disbursing funds via third-party accounts and excludes direct transfers from transferees to transferors and disbursements coming directly from banks.

Fourth, *the person that prepares an evaluation of the title status*—In the event that no person participates in the transfer who falls within the first three tiers of the cascade, the reporting person would be the person who prepares an

¹⁰⁹ The types of businesses involved in a real estate closing or settlement vary depending on the type of transaction and on the jurisdiction. As such, the reporting cascade (see Proposed amendments *infra* 31 CFR 1031.320(c)) is itemized to capture a broad array of potential businesses. However, FinCEN believes that, for any transaction, the functions described in first three tiers of the reporting cascade would be performed by only one business, with no other separate business performing the other two functions. FinCEN therefore treats the reporting cascade as having five functional groupings.

¹⁰⁸ See, e.g., U.S. Department of the Treasury, National Strategy for Combatting Terrorist and Other Illicit Financing (2020), pp. 17–18, available at <https://home.treasury.gov/system/files/136/National-Strategy-to-Counter-Illicit-Financev2.pdf>.

¹¹⁰ The U.S. title insurance market is concentrated, with four national underwriters accounting for approximately 81 percent of total industry premiums as September 2022. Fitch Rating, U.S. Title Insurance Outlook 2023 (Dec. 2, 2022), available at <https://www.fitchratings.com/research/insurance/us-title-insurance-outlook-2023-02-12-2022>.

evaluation of the status of the title. Such an evaluation may take the form of a title check, which is typically performed by title insurance companies in lieu of providing actual insurance or an opinion letter, which is rendered by attorneys.

Fifth, *the person who prepares the deed*—Finally, should no person identified in the first four tiers of the cascade participate in the real property transfer, the reporting obligation would fall to the preparer of the deed associated with the transfer. A deed is typically prepared by an attorney, but it may also be prepared by a non-attorney settlement or closing agent or by the transferee itself.

2. Capturing Both Sale and Non-Sale Transfers

The reporting cascade is designed to capture both sales of residential real estate and non-sale transfers of residential real estate. It assigns a reporting obligation based on the functions fulfilled by the various real estate professionals involved in the closing and settlement process, regardless of whether the transfer is a sale or non-sale. FinCEN believes that it is necessary to capture non-sale transfers to ensure uniform coverage of non-financed transfers and to ensure that nominees do not purchase homes for criminal actors and then transfer the title on free of charge to a legal entity or trust.

During a typical closing and settlement for a non-financed transfer of residential real estate, a transferee will offer to purchase a residential real property for a given price. This offer can occur through a representative, such as a real estate agent, attorney, or registered agent, or it may come directly from the transferee itself. If the transferor accepts the offered price, either directly or through a representative, the parties can proceed toward the settlement process, normally through a sales contract. It is at this point that title agencies or companies and escrow agents or companies typically become involved in the process. Title agencies will conduct an examination of the title to ensure it is free from defects, such as liens or other encumbrances. Escrow companies may at this point hold a deposit or “earnest money” from the transferee that the transferee would forfeit should it be responsible for breaking the purchase contract.¹¹¹ A transferee may also, and

usually does, purchase a title insurance policy, which ensures that the title of the property is free from defects and indemnifies the transferee should a title defect later come to light. As noted above, a transferee may opt, in lieu of title insurance, to obtain a title check from the title insurance company or an opinion letter from an attorney.¹¹² However, neither title insurance nor a title check is required to close or settle non-financed transfers of residential real property.

The transfer can then move toward settlement, which is also sometimes referred to as “closing.” According to ALTA, settlement is “[t]he process of completing a real estate transaction in accordance with written instructions during which deeds, mortgages, leases, and other required instruments are executed and/or delivered, an accounting between the parties is made, the funds are disbursed, and the appropriate documents are recorded in the public record.”¹¹³ At settlement, a closing or settlement agent—which is most often a title agent but can be a representative of an escrow company or an attorney—will prepare a “settlement statement,” which normally contains an itemized list of all of the fees or charges that the buyer and seller will pay during the settlement portion of the transfer.¹¹⁴ At settlement, the settlement statement and other closing documents are signed by the parties to the transfer and, if applicable, funds are disbursed to the

custom.” American Land Title Association, ALTA Best Practices 4.0 (May 23, 2023), p. 4, available at <https://www.alta.org/best-practices/download.cfm?bestPracID=97&type=pdf>.

¹¹² DarrowEverett LLP, “Are Attorney Opinion Letters a Viable Alternative to Title Insurance” (Feb. 23, 2023), available at <https://www.darroweverett.com/attorney-opinion-letter-advantages-risks-title-insurance/>; Fannie Mae, B7–2–06, Attorney Title Opinion Letter Requirements: Attorney Title Letter Opinion Requirements (Dec. 13, 2023), available at <https://selling-guide.fanniemae.com/Selling-Guide/Origination-thru-Closing/Subpart-B7-Insurance/Chapter-B7-2-Title-Insurance/2522435591/B7-2-06-Attorney-Title-Opinion-Letter-Requirements-04-06-2022.htm>.

¹¹³ American Land Title Association, ALTA Best Practices 4.0 (May 23, 2023), p. 4, available at <https://www.alta.org/best-practices/download.cfm?bestPracID=97&type=pdf>.

¹¹⁴ “The title agent and settlement agent are often the same entity that performs two separate functions in a real estate transaction. The terms title agent and settlement agent are often used interchangeably.” American Land Title Association, “ALTA Urges CFPB to Preserve Role of Independent Third-party Settlement Agents” (Nov. 8, 2012), p. 26, available at <https://www.alta.org/news/news.cfm?20121108-ALTA-Urges-CFPB-to-Preserve-Role-of-Independent-Third-party-Settlement-Agents>; see, e.g., American Land Title Association, “ALTA Model Settlement Statements,” available at <https://www.alta.org/trid/#statements>; Consumer Finance Protection Bureau, What is a HUD–1 Settlement Statement? (Sept. 4, 2020), available at <https://www.consumerfinance.gov/ask-cfpb/what-is-a-hud-1-settlement-statement-en-178/>.

transferor. This typically occurs via an escrow account, but also occurs at times via a trust account or attorney trust account or via a direct transfer of funds between the transferee and transferor (though, due to its risky nature, this practice is not common). Following the execution of the settlement statement and other closing documents and the disbursement of funds, the settlement agent will file the deed (the instrument which effects the transfer of ownership of the property) with the relevant local land registry or recordation office. Deeds are typically prepared by attorneys, but may be prepared by the settlement agent, escrow officer, or the transferee itself.¹¹⁵

A transfer of residential real estate that does not involve a purchase, such as a transfer that is a gift or that is made to a trust, involves a closing and settlement process that is distinct from the process described above that exists for typical sales of residential real estate. For example, such non-sale transfers would not involve a settlement agent or settlement statement or the transfer of funds through escrow. They may, however, involve an attorney or other real estate professional who prepares or files the deed, provides title insurance, or provides a title evaluation.

3. Designation Agreements

Although the reporting cascade would identify the real estate professional who would be primarily responsible for filing a Real Estate Report, the real estate professionals described in the reporting cascade may enter into a written agreement to designate another person in the reporting cascade as the reporting person. For example, if a real estate professional involved in the transfer provides certain settlement services in the settlement process, as described in the first tier of the cascade, that person may enter into a written designation agreement with a title insurance company underwriting the transfer as described in the second tier of the cascade, through which the two parties agree that the title insurance company would be the designated reporting person with respect to that transfer. The person who would otherwise be the reporting person must

¹¹⁵ See Redfin.com, “Steps to closing on a house,” available at <https://www.redfin.com/guides/steps-to-closing-on-a-house>; American Land Title Association, ALTA Best Practices 4.0 (May 23, 2023), p. 4, available at <https://www.alta.org/best-practices/download.cfm?bestPracID=97&type=pdf>; see generally American Land Title Association, “ALTA Urges CFPB to Preserve Role of Independent Third-party Settlement Agents” (Nov. 8, 2012), available at <https://www.alta.org/news/news.cfm?20121108-ALTA-Urges-CFPB-to-Preserve-Role-of-Independent-Third-party-Settlement-Agents>.

¹¹¹ “Escrow is [a] transaction in which an impartial third-party acts in a fiduciary capacity for all or some of the parties . . . in performing [s]ettlement services according to local practice and

be a party to the agreement; however, it is not necessary that all persons involved in the transfer who are described in the reporting cascade be parties to the agreement.

While the agreement must be in writing and must identify the date of the agreement, the name and address of the transferor, the name and address of the transferee entity or transferee trust, the property, the name and address of the designated reporting person, and the name and address of all other parties to the agreement, there is no required format for the designation agreement. All parties to the agreement would be required to retain a copy for a period of five years.

4. Employees, Agents, and Partners

If an employee, agent, or partner acting within the scope of such individual's employment, agency, or partnership would be the reporting person in a reportable property transfer, then the individual's employer, principal, or partnership is deemed to be the reporting person. In that case, it is the responsibility of the reporting person (*i.e.*, the employer, principal, or partnership) to ensure that a report is filed. Accordingly, FinCEN expects that, in most cases, individuals will not be reporting persons. However, there may be certain cases (*e.g.*, sole proprietorships) where the responsibility to file a report rests with an individual.

5. Consultations With Real Estate Professionals

The cascade is designed to both prevent an increased burden on reporting persons by ensuring that multiple real estate professionals do not have to collect information and file a report about the same transfer, while at the same time minimizing opportunities for reporting evasion by ensuring a report is filed for most reportable transfers. In the course of developing this cascading reporting order, FinCEN held extensive discussions with real estate professionals and the IRS, which employs a somewhat similar cascading reporting structure for its Form 1099-S.¹¹⁶ These discussions suggest that potential reporting persons involved in a real estate closing or settlement would be aware of one another's presence or absence in the process at the time of closing, and that the reporting chain would be easily interpreted by persons

involved in real estate closings and settlements.

Several 2021 ANPRM commenters suggested the use of a reporting cascade.¹¹⁷ Some commenters recommended that title and escrow companies and agents, real estate agents and brokers, real estate attorneys, and other real estate professionals be the reporting persons in any potential regulation, to ensure that a broad swath of real estate professionals are included and to prevent reporting loopholes.¹¹⁸ One commenter suggested that title insurance companies that are already affiliated with heavily regulated financial institutions, such as banks, should not be required to report; FinCEN is not proposing this path because it is unclear who would decide this or how it would be determined.¹¹⁹ Another commenter stated that FinCEN should place any compliance

obligations on the seller, but FinCEN believes this would place too much burden on individuals who are not real estate professionals.¹²⁰ Two commenters suggested requiring only title insurance companies to report in the residential context, and only secondarily requiring escrow agents to report if title insurance is not purchased.¹²¹

Rather than to include or exclude any particular persons involved in real estate settlements and closings based on the titles they hold, FinCEN decided to design a reporting cascade based on the functions performed in a closing or settlement. This functional approach will ensure that the professional closest to the proposed information to be reported is most often the reporting person, thereby increasing efficiency and lessening overall burden. FinCEN notes that, as a result of this functional approach, specific real estate professionals such as real estate agents, brokers, and attorneys are not directly subject to obligations in the reporting cascade. They acquire reporting obligations only if they perform the specified functions.

Several commenters on the 2021 ANPRM argued against inclusion of attorneys, claiming that attorney-client privilege should prevent attorneys involved in real estate closings and settlements from reporting information, including beneficial ownership information.¹²² In this proposed rule, FinCEN would require reporting by attorneys only when they perform certain functions—functions that generally may be performed by non-attorneys. Although some jurisdictions in the United States require a licensed attorney to perform certain closing or settlement functions, FinCEN believes that the functions described in the cascade may generally be performed by both attorneys and non-attorneys. Indeed, FinCEN believes that the same reporting obligations should apply to

¹¹⁷ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), p. 11, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 10, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; Senator Sheldon Whitehouse, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0118>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; National Association of Realtors, ANPRM Comment (Feb. 18, 2022), p. 15, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0128>.

¹¹⁸ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), p. 11, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; League of Southeastern Credit Unions & Affiliates, ANPRM Comment (Feb. 7, 2022), pp. 3–4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0011>; American Land Title Association, ANPRM Comment (Feb. 17, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0020>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 10, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; American Escrow Association, ANPRM Comment (Feb. 18, 2022), pp. 13–17, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0124>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Illinois Credit Union League, ANPRM Comment (Feb. 21, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0137>; Palmera Consulting, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0141>; Louise Shelley and Ross Delston, ANPRM Comment (Feb. 21, 2022), p. 2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0151>.

¹¹⁹ See Prosperus Title, ANPRM Comment (Feb. 18, 2022), p. 1, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0125>.

¹²⁰ See Morgan, Lewis, & Bockius, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0123>.

¹²¹ See Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 1, 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>; National Association of Realtors, ANPRM Comment (Feb. 18, 2022), p. 14, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0128>.

¹²² See Joint Editorial Board for Uniform Real Property Acts, ANPRM Comment (Feb. 5, 2022), pp. 1–2, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0014>; American Bar Association, ANPRM Comment (Feb. 7, 2022), pp. 1–12, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0018>; Marisa N. Bocci, ANPRM Comment (Feb. 21, 2022), p. 5, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0150>.

¹¹⁶ See 29 CFR 1.6045–4 (Information reporting on real estate transactions with dates of closing on or after January 1, 1991).

attorneys and non-attorneys alike when they perform the same functions in reportable transfers of residential real property. Furthermore, FinCEN expects that reporting of factual information about a real estate transfer would not implicate attorney-client privilege, in most cases. Also, the proposed rule provides that potential reporting persons, including attorneys, may enter into designation agreements with other real estate professionals described in the cascade, thereby passing the reporting obligation to another professional.

E. Information To Be Reported

1. Description of Information

The proposed rule requires reporting persons to report and maintain records of certain information regarding reportable transfers. This includes certain information about any reporting persons, transferee entities, transferee trusts, signing individuals, transferors, the residential real property, and reportable payments. To a large degree, this information is similar to the transactional information required to be reported through traditional SARs. FinCEN emphasizes that Real Estate Reports, like SARs, would be housed in FinCEN's secure BSA Portal and would not be accessible to the general public; FinCEN imposes strict limits on the use and re-dissemination of the data it provides to its law enforcement and other agency partners.

The following discussion addresses in more detail some of the types of information the rule proposes to collect.

1. *Name and address:* The proposed rule would collect the name and address of the principal place of business for reporting persons, transferee entities and transferee trusts, and transferors that are entities. For legal entities that are trustees of transferor trusts, the proposed rule would collect the place of trust administration. It would collect the name and a residential address for each individual who signed documents on behalf of the transferee (signing individuals), all beneficial owners of a transferee entity or transferee trust, individual transferors, and individuals who are trustees of transferor trusts.

2. *Citizenship:* The proposed rule would collect citizenship information for all beneficial owners of a transferee entity or transferee trust. FinCEN proposes to collect this information to better analyze the volume of illicit funds entering the United States via entities or trusts beneficially owned by non-U.S. persons. FinCEN cannot do this type of broad analysis without collecting citizenship information. For instance, traditional SARs already collect this

type of information and FinCEN was able to analyze SARs in aggregate to identify Russian investment in the U.S. economy, including the real estate sector, after the invasion of Ukraine.¹²³

3. *Unique identifying number:* The proposed rule would collect a unique identifying number for each person (whether an individual or entity) whose name and address are required to be reported. For any individual for whom a unique identifying number would be collected, a unique identifying number can be an IRS Taxpayer Identification Number (TIN) or, if they do not have one, a foreign equivalent or a foreign passport number. For an entity, a unique identifying number can be an IRS TIN or, if the entity does not have one, a foreign equivalent or a foreign registration number. FinCEN chose to include the collection of TINs, such as Social Security Numbers (SSNs) or Employer Identification Numbers (EINs), for transferee entities, transferee trusts, beneficial owners of transferee entities and trusts, as well as for certain individuals signing documents on behalf of the transferee entity or trust during the residential real estate transfer, for a number of reasons. Reporting TINs provides law enforcement with the most efficient means to identify potential individuals involved in illicit activity and connect those persons to other transactions during investigations. Unlike names, addresses, and dates of birth, which can be common across multiple individuals, TINs are unique to a given individual, entity, or trust. Consequently, collections of TINs would cut down on flagging of individuals, entities, and trusts that are not the intended subject of an investigation, which will allow law enforcement to more efficiently pursue leads, conduct investigations, and identify illicitly acquired assets. FinCEN's consultations with law enforcement have confirmed that law enforcement views access to TIN information as extremely helpful for streamlining investigative work. Law enforcement officials also indicated to FinCEN that it is relatively easy for illicit actors to create a false identity

¹²³ See FinCEN, FIN–2023–Alert002, FinCEN Alert on Potential U.S. Commercial Real Estate Investments by Sanctioned Russian Elites, Oligarchs, and their Proxies (Jan. 25, 2023), available at https://www.fincen.gov/sites/default/files/shared/FinCEN%20Alert%20Real%20Estate%20FINAL%20508_1-25-23%20FINAL%20FINAL.pdf; FinCEN, FIN–2022–Alert002, FinCEN Alert on Real Estate, Luxury Goods, and Other High-Value Assets Involving Russian Elites, Oligarchs, and their Family Members (Mar. 16, 2022), available at https://www.fincen.gov/sites/default/files/2022-03/FinCEN%20Alert%20Russian%20Elites%20High%20Value%20Assets_508%20FINAL.pdf.

using a combination of name, address, and date of birth, and often do so, thereby impeding an investigation from the outset. However, law enforcement noted that obtaining a false TIN was orders of magnitude more difficult and that collection of such information was therefore crucial to their investigations. Moreover, TINs are routinely collected in other BSA reports, including SARs.¹²⁴ Accordingly, the proposed rule would collect TINs for certain persons involved in covered residential real estate transfers.

4. *Representative capacity of signing individual:* For any signing individual, the proposed rule would collect a description of the capacity in which the individual is authorized to act as the signing individual for the transferee entity or transferee trust, such as whether the signing individual is a legal representative. Additionally, if the signing individual is acting in that capacity as an employee, agent, or partner, the proposed rule would collect the name of the employer, principal, or partnership.

5. *Information concerning payments:* The proposed rule would collect the total consideration paid by *all* transferees regarding the residential real property, as well as the total amount paid by the transferee entity or trust, the method of each payment made by the transferee entity or transferee trust, the accounts and financial institutions used for each such payment, and, if the payor is anyone other than the transferee entity or transferee trust, the name of the payor on the payment form. With respect to the reporting of payments made by the transferee entity or transferee trust, the proposed rule seeks only to capture transactions where the greatest risk for money laundering is present—the movement of funds from accounts held or controlled by the transferee—and therefore exempts payments made from escrow or trust

¹²⁴ FinCEN, FinCEN Suspicious Activity Report (FinCEN SAR) Electronic Filing Requirements (Aug. 2021), p. 62, available at https://bsaeifiling.fincen.treas.gov/docs/XMLUserGuide_FinCENSAR.pdf; see also FinCEN, Report of Cash Payments Over \$10,000 Received in a Trade or Business (FinCEN Form 8300) Electronic Filing Requirements (Aug. 2021), p. 28, available at https://bsaeifiling.fincen.treas.gov/docs/XMLUserGuide_FinCEN8300.pdf (indicating Form-8300s require TINs to be reported); FinCEN, FinCEN Currency Transaction Report (CTR) Electronic Filing Requirements (Aug. 2021), p. 27, available at https://bsaeifiling.fincen.treas.gov/docs/XMLUserGuide_FinCENCTR.pdf (indicating CTRs required TINs to be reported); FinCEN, FinCEN Report of Foreign Bank and Financial Accounts (FBAR) Electronic Filing Requirements (Aug. 2021), p. 29, available at https://bsaeifiling.fincen.treas.gov/docs/XMLUserGuide_FinCENFBAR.pdf (indicating FBARs require TINs to be reported).

accounts held by the reporting person. Accordingly, the rule would require the reporting of payments made *from other* escrow or trust accounts, payments made *into any* escrow or trust accounts (to prevent illicit actors from trying to circumvent the reporting requirement), and payments sent directly from the transferee to the transferor. For example, if the payment path is (1) from the transferee's bank account to a trust account, (2) from that trust account to an escrow account held by the reporting person, and then (3) from that escrow account to the transferor, the reporting person would need to provide the payment details of the first leg of the payment path. FinCEN notes that the reporting requirement would include the reporting of payments that the reporting person may consider as being paid outside of closing, such as a payment made between a buyer and seller through bank accounts located outside of the United States. FinCEN proposes to collect payment information because financial information is key to ensuring that the reports meet the threshold for being highly valuable to law enforcement. The payment information behind real estate transfers conducted in a manner that has been identified as high risk for money laundering would help support law enforcement investigations, as it can help connect beneficial owners to suspicious activity or funding sources. The collection of this information may also serve as a deterrent to those thinking about attempting to launder money through the U.S. residential real estate sector.

6. Information concerning the residential real property: The proposed rule would require the address of the relevant property, if applicable, and a legal description, such as the section, lot, and block. This information would be reported for each property involved in the transfer. For example, if a four-unit town home is transferred to a transferee entity, all four addresses would be reported.

Commenters on the 2021 ANPRM had diverse views on what information should or should not be collected under any potential regulation. Most commenters who thought that information should be collected were in favor of collecting transferee side information, including beneficial ownership information.¹²⁵ However,

other commenters said that only basic information that is already collected in the course of a closing about the transferee should be collected, and that requiring real estate professionals to collect beneficial ownership information would be too burdensome.¹²⁶ FinCEN recognizes that while most of the information that would be collected under this proposed rule is provided to the most frequent reporters in the normal course of a closing, beneficial ownership information is not. FinCEN addressed concerns about the burden of collecting beneficial ownership information in this proposed rule by making sure that reporting persons can collect this information through a form, which is then certified by the transferee as being accurate, as will be discussed further below.

Some commenters advocated for the collection of transferor information as well.¹²⁷ FinCEN opted to collect only minimal transferor information, as the primary party of interest to law enforcement is the new owner of property that has been transferred in a manner that presents money laundering concerns.

Commenters also mentioned collecting certain funds payment information,¹²⁸ identifying PEPs

¹²⁵ See American Land Title Association, ANPRM Comment (Feb. 17, 2022), pp. 2–4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>.

¹²⁶ See American Land Title Association, ANPRM Comment (Feb. 17, 2022), pp. 2–4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; American Escrow Association, ANPRM Comment (Feb. 18, 2022), pp. 13–17, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0124>.

¹²⁷ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 27–28, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Senator Sheldon Whitehouse, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0118>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Coalition for Integrity, ANPRM Comment (Feb. 21, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0127>.

¹²⁸ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 27–28, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; Senator Sheldon Whitehouse, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0118>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0124>.

involved in the transfer,¹²⁹ beneficial ownership verification,¹³⁰ information about the property being transferred,¹³¹ and any representatives of the transferee in the transfer.¹³² Elements of each of these are included in the proposed rule, except for PEP identification and beneficial owner verification, which FinCEN believes would require reporting persons to undertake independent research that would represent a dramatically increased burden, compared to collecting information from the transferee.

2. Collection of Information

FinCEN expects that the reporting person will have access to some, but not all, of the reportable information in the normal course of business. In particular, the reporting person may not have on hand the identifying information for the beneficial owners of the transferee entity or trust. The proposed rule therefore includes guidelines for how the reporting person should collect this information.

The reporting person may collect the information directly from a transferee or a representative of the transferee, so long as the person certifies that the

¹²⁹ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 27–28, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 9, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>; The FACT Coalition, ANPRM Comment (Feb. 18, 2022), p. 4, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0122>; California Reinvestment Coalition, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>.

¹³⁰ See Transparency International U.S., ANPRM Comment (Feb. 18, 2022), p. 9, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>.

¹³¹ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 44–45, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; American Land Title Association, ANPRM Comment (Feb. 17, 2022), p. 6, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0126>; Anti-Corruption Data Collective, ANPRM Comment (Feb. 18, 2022), p. 3, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0153>.

¹³² See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 44–45, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; American Escrow Association, ANPRM Comment (Feb. 18, 2022), p. 16, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0124>.

¹²⁵ See Global Financial Integrity, ANPRM Comment (Feb. 17, 2022), pp. 27–28, 44–45, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0102>; Transparency International U.S., ANPRM Comment (Feb. 18, 2022), pp. 8–9, available at <https://www.regulations.gov/comment/FINCEN-2021-0007-0115>.

information is correct to the best of their knowledge. The certification may be collected using a form that may be provided by FinCEN, similar to the one provided with respect to the CDD Rule, which requires certain financial institutions collect beneficial ownership information from legal entity customers, or the reporting person may incorporate a certification into a document of their own design, including existing closing documents used by the reporting person.¹³³

FinCEN could have proposed that reporting persons must personally conduct extensive research to verify beneficial ownership and other information provided to them, but is proposing the use of a certification due to its comparative lesser burden on filers. The use of certifications will also ensure uniform information collection standards are met across reportable transfers. Any certification form signed in the course of a transfer must be retained by the reporting person for five years. Although the reporting person may rely on the information collected from other parties as described above, the reporting person may not report information that the reporting person knows, suspects, or has reason to suspect is inaccurate or incomplete. As an alternative, FinCEN considered requiring reporting persons to undertake the verification of the information to be reported. However, FinCEN is instead proposing the use of a written certification form because this approach would present a lower burden on reporting persons when compared with a scenario in which they would independently verify information through their own research. Allowing parties to the transfer and their representatives to provide information directly, while attesting to its accuracy, will reduce time and resources expended by reporting persons while ensuring that the most accurate information is provided to law enforcement and that compliance can be monitored more effectively. The proposed rule would also allow the flexibility of the reporting person collecting the information by any other means, so long as the transferee's representative (whether a signing individual or other type of representative) attests to its accuracy.

F. Filing Procedures

A reporting person must electronically file a Real Estate Report with FinCEN, following the reporting form's instructions, no later than 30 calendar days after the date on which

the transferee entity or transferee trust receives the ownership interest in the residential real property. This is to ensure that reporting of time sensitive information about residential real estate closings and settlements is not unduly delayed.

G. Records Retention

Reporting persons must maintain a copy of any Real Estate Report they have filed and any certifications as to the identities of the beneficial owner(s) of a transferee entity or transferee trust for five years from the date of filing and keep them available at all times for inspection as authorized by law.

All parties to a designation must similarly retain a copy of the agreement for five years from the date of signing and keep it available at all times for inspection as authorized by law.

H. Exemptions

The proposed rule would exempt reporting persons and Federal, State, local, or Tribal government authorities from the confidentiality provision in 31 U.S.C. 5318(g)(2) prohibiting the disclosure to any person involved in the transaction that the transaction has been reported.¹³⁴ As noted above, FinCEN recognizes that financial institutions who file SARs are subject to restrictions prohibiting the disclosure of the existence of the SAR to any of its subjects. However, this would not be feasible with the proposed Real Estate Report, as reporting persons would need to collect information directly from the subjects of the Report. Moreover, all parties to a non-financed residential real estate transfer that is subject to the proposed rule would already be aware that a report would be filed, given that such filing is non-discretionary, rendering confidentiality unnecessary.

Furthermore, persons involved in real estate closings and settlements are exempt from the requirement to maintain an AML program requirement.¹³⁵ For the reasons discussed earlier, that exemption will continue to apply to persons involved in real estate closings and settlements under the proposed rule. However, the exemption does not apply to reporting persons who are financial institutions otherwise required to establish an AML/CFT program under FinCEN's regulations.

V. Final Rule Effective Date

FinCEN is proposing an effective date of one year from the date the final rule

is issued. A one-year effective date is intended to provide real estate professionals with sufficient time to review and prepare for implementation of the rule. FinCEN solicits comment on the proposed effective date for this rule.

VI. Request for Comment

FinCEN seeks comments on the questions listed below, but invites any other relevant comments as well. FinCEN encourages commenters to reference specific question numbers to facilitate FinCEN's review of comments.

1. What would the cost and hour burden of filing reports as detailed by this NPRM be for your profession? Please quantify, if possible, the anticipated burden this proposed rule would represent for the designated reporting persons.

2. What percentage of residential real property transfers involve transfers to the types of entities described in the regulation as "transferee entities" and "transferee trusts"?

3. What are the benefits and drawbacks to having a cascading hierarchy of reporting persons, as proposed?

4. Will real estate professionals know or be able to discover the other real estate professionals performing functions in the closing process as laid out by the reporting cascade?

5. Please provide feedback on the order of the proposed cascading reporting hierarchy. Does it include those real estate professionals who are most able to obtain and report the required information? Should any person involved in real estate closings and settlements present in the proposed cascade be removed? Added? Why?

6. Are there potential loopholes in the proposed cascading reporting order? If so, how might they be overcome? For example, would specifically adding real estate agents and brokers close any reporting gaps?

7. How likely are potential reporting persons to enter into designation agreements? Are there any particular challenges associated with entering into such an agreement? With documenting that such an agreement has been made?

8. What are typical costs to close a residential real estate deal? What percentage of the sale price do these costs typically represent?

9. What sort of due diligence is normally conducted, before or at closing for residential properties, regarding (i) the parties to a transfer; (ii) the source of funds for any transfer; and (iii) other key aspects of the transfer?

10. What sort of existing recordkeeping or reporting requirements, unrelated to BSA

¹³⁴ 31 U.S.C. 5318(a)(7) (which allows the Secretary to prescribe appropriate exemptions).

¹³⁵ 31 CFR 1010.205(b)(1)(v).

¹³³ See 31 CFR 1010.230.

compliance, exist for non-financed residential real estate transfers? If any, what information must be recorded or reported, to whom, and for how long? What entity provides oversight?

11. Should FinCEN limit the scope of any final rule to only non-financed transfers? What are the benefits and drawbacks to doing so?

12. What adjustments, if any, should be made to the proposed definition of a reportable transfer?

13. Should the rule except transfers that involve a qualified extension of credit to “all” transferees or to “any” transferee?

14. What percentage of residential real estate transfers are non-financed?

15. What adjustments, if any, should be made to the proposed definition of “residential real property”? Is the description of such property as “designed principally for occupancy by one to four families” a clear industry standard?

16. Are the beneficial owners of transferee entities or transferee trusts routinely identified by some participant in the transfer?

17. What information, if any, should be reported about transfers involving tax-exempt organizations?

18. What do persons involved in real estate closings and settlements do if they have any suspicions about a transfer of residential real property, customer, or the payments supporting the transfer?

19. What roles do attorneys play in non-financed sales and non-sale transfers of residential real estate? Are there attorney-client privilege concerns with reporting these transfers, as proposed in the rule? If so, what is the basis for these concerns?

20. Please describe the purpose of the use of an escrow account, trust account, or lawyers’ trust account in a real estate transfer. Do these accounts present money laundering concerns? Is the use of these accounts sufficiently captured in the proposed rule? Are there attorney-client privilege concerns around the use of lawyer’s trust accounts, and if so, what is the basis for these concerns?

21. How are opinion letters used in the real estate closing and settlement process? Are there attorney-client privilege concerns around the use of opinion letters? If so, what is the basis for those concerns?

22. Are there other attorney-client privilege concerns, such as around attorneys acting as settlement agents, drafting or filing deeds, or reporting any of the required information? What is the basis for those concerns?

23. How do factors related to parties to the transfer, the payments related to the transfer, and the property itself bear on money laundering risk assessment? What kinds of transfers and customers are highest and lowest risk? How are those risks mitigated and what are the associated costs of that mitigation?

24. Is it possible to estimate the extent to which residential real property values are affected by money laundering through real estate?

25. Please provide comments on the proposed definition of transferee entity.

26. Please provide comments on the proposed definition of transferee trust.

27. Please provide comments on the proposed definition of beneficial owners of transferee entities.

28. Please provide comments on the proposed definition of beneficial owners of transferee trusts.

29. Please provide comments on any other definition in the proposed rule.

30. Please provide comments on the proposed coverage of transfers of residential real estate to transferee entities and transferee trusts, including the benefits and drawbacks to covering each.

31. Are there any areas within the geographic scope of this proposed rule that have unique customs or requirements that should be taken into account?

32. Please comment on how aware real estate professionals involved in residential real property transfers are of other categories of real estate professionals that may be involved in a given closing or settlement.

33. What are the benefits of the rule as proposed?

34. Is the information FinCEN proposes to be reported regarding non-financed residential real estate transfers to transferee entities and transferee trusts sufficient, over- or under-inclusive? What information should be added or removed and why?

35. Should FinCEN ask for citizenship information of beneficial owners of transferee entities and transferee trusts? Why or why not?

36. Is the information FinCEN proposes to be reported regarding reporting persons sufficient, over- or under-inclusive? What information should be added or removed and why?

37. Please provide comments on the proposed collection of TINs for transferors and transferees and their beneficial owners.

38. Is the information FinCEN proposes to be reported regarding signing individuals sufficient, over- or under-inclusive? What information should be added or removed and why?

39. Is the information FinCEN proposes to be reported regarding

transferors sufficient, over- or under-inclusive? What information should be added or removed and why?

40. Is the information FinCEN proposes to be reported regarding the description of the transferred property sufficient, over- or under-inclusive? What information should be added or removed and why?

41. Is the information FinCEN proposes to be reported regarding payments sufficient, over- or under-inclusive? What information should be added or removed and why? Would it be useful to reporting persons to have space on the reporting form to explain or discuss suspected or observed suspicious activity?

42. Should FinCEN require information regarding additional information about the source of funds for covered residential real estate transfers? How would or should reporting persons go about ascertaining source of funds information?

43. How should FinCEN consider real estate transfers to foreign trusts and charitable trusts? Foreign non-profits? Do these present sufficient money laundering risk that they should be covered by any final rule? Why or why not?

44. If program or other requirements were limited to purchases above a certain price threshold, how would this affect: (i) the burden of implementing such potential rules; and (ii) the utility of such potential rules for addressing money laundering issues in the real estate market?

45. What are the key benefits for a reporting person, if any, assuming issuance of the rules?

46. Please list any legislative, regulatory, judicial, corporate, or market-related developments that have transpired since FinCEN issued the 2021 ANPRM that you view as relevant to FinCEN’s current proposed issuance of AML regulations.

47. Are there particular concerns that small businesses may have regarding the implementation of this proposed rule?

48. What would be the value of covering partially non-financed residential real estate transfers? What level of financing would be sufficient to alleviate that concern?

49. FinCEN understands that for certain residential real estate transfers involving multiple investors, such as with unregistered PIVs, or large operating companies, there may be multiple financing methods involved in a single residential transfer. Please detail in the context of the proposed rule how due diligence checks on partially financed residential real estate transfers involving multiple entities

may differ from due diligence checks on fully financed residential real estate transfers multiple entities.

50. This NPRM is focused on residential real estate. Do the same considerations for type of purchaser covered and professionals required to report apply to the commercial real estate sector?

VII. Regulatory Analysis

This regulatory impact analysis (RIA) evaluates the anticipated effects of the proposed rule in terms of its expected costs and benefits to affected parties, among other economic considerations, as required by Executive Orders 12866, 13563, and 14094 (E.O. 12866 and its amendments).¹³⁶ This RIA also includes assessments of the potential economic impact on small entities pursuant to the Regulatory Flexibility Act (RFA) and reporting and recordkeeping burdens under the Paperwork Reduction Act of 1995 (PRA), as well as analysis required under the Unfunded Mandates Reform Act of 1995 (UMRA).¹³⁷

As discussed in greater detail below, the proposed rule is expected to promote national security objectives¹³⁸ and enhance compliance with international standards¹³⁹ by improving law enforcement's ability to identify the natural persons associated with transactions conducted in the U.S. residential real estate sector and thereby diminish the ability of corrupt and other illicit actors to launder their proceeds through real estate purchases in the United States. More specifically, the collection of the proposed streamlined SARs, Real Estate Reports, in a repository that would be readily accessible to law enforcement is expected to increase the efficiency with which resources can be utilized to identify such natural persons, or

beneficial owners, when they have conducted non-financed purchases of residential real property using legal entities or trusts.

The following RIA first describes the economic analysis FinCEN undertook to inform its expectations of the proposed rule's impact and burden.¹⁴⁰ This is followed by certain pieces of additional and, in some cases, more specifically tailored analysis as required by E.O. 12866 and its amendments,¹⁴¹ the RFA,¹⁴² the UMRA,¹⁴³ and the PRA,¹⁴⁴ respectively. Requests for comment related to the RIA—regarding specific findings, assumptions, or expectations, or with respect to the analysis in its entirety—can be found in the final subsection¹⁴⁵ and have been previewed and cross-referenced throughout the RIA.

A. Assessment of Impact

This proposed rule has been determined to be a “significant regulatory action” under Section 3(f) of Executive Order 12866 because it may raise legal or policy issues. The following assessment indicates that the proposed rule may also be considered significant under Section 3(f)(1), as the proposed rule is expected to have an annual effect on the economy of \$200 million or more.¹⁴⁶ Consistent with certain identified best practices in regulatory analysis, the economic analysis conducted in this section begins with a review of FinCEN's broad economic considerations, identifying the relevant market failures (or fundamental economic problems) that demonstrate the need or otherwise animate the impetus for the policy intervention as proposed.¹⁴⁷ Next, the analysis turns to details of the current regulatory requirements and the background of market practices against which the proposed rule would introduce changes and establishes baseline estimates of the number of entities and residential real property transactions FinCEN expects could be affected in a given year. The analysis then briefly reviews the content of the proposed rules with a focus on the specifically relevant elements of the proposed definitions and requirements

that most directly inform how FinCEN contemplates compliance with the proposed requirements would be operationalized. Next, the analysis proceeds to outline the estimated costs to the respective affected parties that would be associated with such operationalization. Finally, the analysis concludes with a brief discussion of certain alternative policies FinCEN considered and could have proposed, including an evaluation of the relative economic merits of each against the expected value of the rule as proposed.

1. Broad Economic Considerations

The proposed rule principally addresses two broad problems. First, is the problematic use of the United States' residential real estate market to facilitate money laundering and illicit activity. Second, and related, is the difficulty of determining who beneficially owns legal entities or trusts that may engage in non-financed transactions, either because this data is not available to law enforcement or access is not sufficiently centralized to be meaningfully usable for purposes of market level risk-monitoring or swift investigation and prosecution. The second problem contributes to the first, making money laundering and illicit activity through residential real property more difficult to detect and prosecute, and thus more likely to occur. Although FinCEN is unable to quantify the economic benefits of the proposed rule, FinCEN expects that the proposed rule would generate benefits by mitigating those two problems. In other words, FinCEN expects that the proposed rule could make law enforcement investigations of illicit activity and money laundering in residential real estate less costly and more effective, and it would thereby generate value in the reduction of social costs associated with such activity.

a. The Problem of Money Laundering and Illicit Activity via Residential Real Property

First, and most significantly, real estate money laundering can facilitate a broad range of illicit activity, and such activity entails significant social costs. For example, crimes such as tax evasion deprive governments of funds that could otherwise be used for public services or infrastructure investment.¹⁴⁸ Other crimes such as financial fraud deprive

¹³⁶ See *infra* Section VII.B.

¹³⁷ Pursuant to its UMRA-related analysis, FinCEN has not anticipated material changes in expenditures for State, local, and Tribal governments, but because the proposed rule would impose new reporting and recordkeeping requirements on select entities in the private sector in connection with certain residential property transfers, FinCEN considers expenditures these private entities may incur as part of the regulatory impact in its assessment below.

¹³⁸ See The White House, United States Strategy on Countering Corruption (Dec. 6, 2021), available at <https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-on-Countering-Corruption.pdf>.

¹³⁹ See Financial Action Task Force, The FATF Recommendations (Feb. 2012; last updated Nov. 2023), available at <https://www.fatf-gafi.org/en/publications/Fatfrecommendations/Fatfrecommendations.html>; see also Financial Action Task Force, United States Mutual Evaluation Report (Dec. 2016), p.1., available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/mer/MER-United-States-2016.pdf.coredownload.inline.pdf>.

¹⁴⁰ See Section VII.A.

¹⁴¹ See Section VII.B.

¹⁴² See Section VII.C.

¹⁴³ See Section VII.D.

¹⁴⁴ See Section VII.E.

¹⁴⁵ See Section VII.F.

¹⁴⁶ Executive Order 12866 (Sept. 30, 1993), section 3(f)(1); see also Section VII.A.4.

¹⁴⁷ Broadly, the anticipated economic value of a proposed rule can be measured by the extent to which it might reasonably be expected to resolve or mitigate the economic problems identified by such review.

¹⁴⁸ Organization for Economic Co-Operation and Development (OECD), Report on Tax Fraud and Money Laundering Vulnerabilities in the Real Estate Sector (2007), available at <https://www.oecd.org/ctp/exchange-of-tax-information/4223621.pdf> (finding that real estate is a preferred choice of criminals for hiding ill-gotten gains and that tax fraud schemes are often closely linked with these activities).

victims of their property, chilling legitimate investment and business activity that can yield economic benefits. Crimes involving various forms of corruption can hinder economic development and discourage legitimate businesses from operating in affected areas.¹⁴⁹ More generally, certain direct and indirect costs of crime include:¹⁵⁰

- funding that must be provided by local, state, tribal, territorial, and Federal Governments to support law enforcement, the judiciary, and correctional services;
- financial losses sustained by crime victims, such as lost money and stolen or damaged property;
- physical, psychological, and long-term financial harm incurred by crime victims and their families, lost productivity and wages, and lower quality of life as a result of victimization; and
- heightened fear of crime, reduced ability to stem blight, loss of commercial and other investment, and increased burden on social service organizations in local communities.¹⁵¹

In addition to facilitating crime and its associated costs, money laundering creates distinct economic problems in the real estate markets in which it occurs. When a market is economically efficient, the public may rely upon the price(s) at which transactions occur to convey meaningful information,¹⁵² in

some cases including information about buyers' and sellers' valuations. Such information enables people to make optimal allocation choices—whether to participate in a given market, what investments to make, or how much to produce, for example. In this setting, money laundering creates price distortion by adding noise to the price signal. When price distortion occurs, the information necessary to make optimal decisions may become difficult or impossible to decipher from observable market behavior. Misallocations of goods and services that harm both producers and consumers may ensue and, in the extreme, markets can break down. Some evidence that this occurs in the real estate market has been documented.¹⁵³

One way to think about how this noise is introduced in the residential real property market is to consider a property transaction by which money is laundered as a bundled good.¹⁵⁴ This would imply that the observable price at which the residential real property is transferred does not reflect simply the buyer's private valuation of the property, but their willingness to pay for money laundering services as well. This implicit bundling can lead to economic inefficiencies in both the number of and counterparties with whom trades occur and the prices at which they occur.

For example, if a residential real property seller is unaware that they are being compensated for both the transfer of their property as well as for their provision of money laundering services, the price at which they agree to the transfer will be inefficiently low.¹⁵⁵ In

the case where such a seller is unwilling to provide money laundering services at any price, this would have caused the bundled price reflecting their private valuations to be infinite, and as such no transaction would have occurred. Another kind of allocative inefficiency could occur if the seller is unable to distinguish between a buyer's price that reflects a bundled value versus one that does not. Allocative efficiency requires that a good be traded with the counterparty whose willingness and ability to pay is highest. Therefore, in a case where a buyer with money laundering intent and a buyer with none both offer to transact at the same price, allocative efficiency would require the seller to trade their residential real property with the buyer without money laundering intent (because their private valuation of the property exceeds that of the money launderer by the proportion of the money launderer's bid that reflects their willingness to pay for money laundering services instead). In cases where this inability to distinguish between buyers of a bundled product versus genuine homebuyers leads to extreme allocative inefficiency, buyers without money laundering intent can be "crowded out" of the residential real property market to deleterious effect.

As a consequence of transactions occurring that inefficiently allocate housing, or transactions occurring at prices that are misaligned with equilibrium market prices, money laundering through residential real property purchases can have disparate effects on regional economic conditions depending on the nature of pre-existing housing supply-demand imbalances in a specific geographic market. For example, by creating additional demand in markets where the quantity of housing demanded already exceeds local supply, transactions for purposes of money laundering can exert additional upward pressure on home prices.

While money laundering may appear to be concentrated in high-end real estate properties and luxury markets, its spillover effects, if left unchecked, could in some instances disproportionately affect low-income and otherwise high-risk communities, undermining other economic policy objectives aimed at helping these

¹⁴⁹ See, e.g., John McDowell and Gary Novis, "The Consequences of Money Laundering and Financial Crime," *Economic Perspectives: An Electronic Journal of the U.S. Department of State*, Focus (May 2001), available at <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwi24f3B5d6AAxUvhlkEHcC4DptlQFnoECBMQAQ&url=https%3A%2F%2Fwww.hsdl.org%2F%3Fview%26did%3D3549&usg=AOvVaw2pg7gw7lpKPhWiw1Nq9mgF&opi=89978449>.

¹⁵⁰ U.S. Department of Justice, Bureau of Justice Statistics, "Costs of Crime," available at <https://bjs.ojp.gov/costs-crime>.

¹⁵¹ For an example in the context of money laundering via commercial real estate, see, e.g., Casey Michel, "A Ukrainian Oligarch Bought a Midwestern Factory and Let it Rot. What Was Really Going On?" *Politico* (Oct. 17, 2021), available at <https://www.politico.com/news/magazine/2021/10/17/ukrainian-oligarch-midwestern-factory-town-dirty-money-american-heartland-michel-kleptocracy-515948> (detailing how a corrupt Ukrainian tycoon laundered hundreds of millions of dollars by purchasing vast stretches of property in an economically depressed community in rural Illinois); see also U.S. Department of Justice, Press Release, Justice Department Seeks Forfeiture of Two Commercial Properties Purchased with Funds Misappropriated from PrivatBank in Ukraine (Aug. 6, 2020), available at <https://www.justice.gov/opa/pr/justice-department-seeks-forfeiture-two-commercial-properties-purchased-funds-misappropriated> (announcing forfeiture actions involving the same Ukrainian oligarch who, the DOJ alleged, purchased hundreds of millions of dollars in real estate and businesses across the country).

¹⁵² For an example of this principle applied to capital asset pricing, see, e.g., Eugene F. Fama,

"Efficient Capital Markets: A Review of Theory and Empirical Work," *The Journal of Finance*, vol. 25, no. 2 (1970), pp. 383–417, available at <https://doi.org/10.2307/2325486>.

¹⁵³ See e.g., European Parliamentary Research Service, "Understanding money laundering through real estate transactions" (Feb. 2019), p. 7, available at [https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/633154/EPRS_BRI\(2019\)633154_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/633154/EPRS_BRI(2019)633154_EN.pdf) (finding that "[d]istortions of real estate prices and the concentration on limited sectors may have an impact beyond those areas and lead to increases in real estate prices, thus pricing people with legal sources of funds out of the market and reduc[ing] housing affordability, something that has been witnessed in several cities in both developed and developing countries . . . resulting in . . . displacement of less affluent households").

¹⁵⁴ For a general description and examples of product bundling, see, e.g., William James Adams and Janet L. Yellen, "Commodity Bundling and the Burden of Monopoly," *The Quarterly Journal of Economics*, vol. 90, no. 3 (1976), pp. 475–98; see also Yongmin Chen, "Equilibrium Product Bundling," *The Journal of Business*, vol. 70, no. 1 (1997), pp. 85–103.

¹⁵⁵ See U.S. Department of the Treasury, National Money Laundering Risk Assessment (Feb. 2022), p. 58, available at <https://home.treasury.gov/system/files/136/2022-National-Money-Laundering-Risk-Assessment.pdf>. Treasury explained in its 2022

National Money Laundering Risk Assessment, "[g]iven the relative stability of the real estate sector as a store of value, the opacity of the real estate market, and gaps in industry regulation, the U.S. real estate market continues to be used as a vehicle for money laundering and can involve businesses and professions that facilitate (even if unwittingly) acquisitions of real estate in the money laundering process" (emphasis added).

communities.¹⁵⁶ As such, money laundering through real estate—though it represents only a relatively small percentage of GDP and takes place in a minority of real estate transfers—can catalyze significant market failures when concentrated in areas that are economically distressed or with low housing volume. In some cases, this distortion can contribute to housing bubbles in affected areas, which may eventually burst and lead to economic instability in impacted regions.¹⁵⁷

b. The Problem of High Search Costs

The U.S. real estate sector is considered an attractive target for money laundering due to several factors that make it conducive to stashing and obscuring the origin of illicit funds.¹⁵⁸ One significant factor is the opacity of beneficial ownership in non-financed real estate transfers to legal entities and trusts. Because these transfers can serve to obscure the identities of beneficial owners, they are acutely vulnerable to exploitation by illicit actors.¹⁵⁹ This mechanism to obfuscate the origin of funds and associated natural persons can effectively incentivize the marginal bad actor to seek new sources of illicit

gain or exploit current sources with greater impunity. Opaque ownership in non-financed real estate transactions can be thought of in economic terms as effectively enhancing the liquidity of ill-gotten funds, thereby increasing the overall profitability of the original activity that engendered a need for money laundering.

Similar economic problems exist when beneficial ownership information and real estate transaction information is available, but search costs to obtain that information are so high as to frustrate or prevent investigative use. To the extent those costs mean that illicit activity is not subsequently investigated or prosecuted, this allows the individual to update their perceived probability of being detected or punished for that illicit activity downward. In a model where the expected value of illicit behavior is a function of both the expected payoff and the risk (or expected severity) of punishment, the problem of high search costs increases the expected value by decreasing the perceived risk of punishment. In cases where the expected value of a certain illicit behavior increases because the anticipated risk or severity of punishment decreased, potential illicit actors may be more likely to engage in such behavior. This updated belief can also lead an individual to mistakenly update their expectations about punishment risk or severity associated with other illegal activities.¹⁶⁰ When this occurs, the coincidence of money laundering and other illicit activity may subsequently rise, which in turn may exacerbate the depressive effects of the original money laundering activities on the local economy in a self-reinforcing cycle.¹⁶¹

¹⁶⁰ This activity is consistent with a representativeness heuristic bias. See Amos Tversky and Daniel Kahneman, “Judgment under Uncertainty: Heuristics and Biases: Biases in judgments reveal some heuristics of thinking under uncertainty,” *Science*, Vol. 185, no. 4157 (1974), pp. 1124–1131.

¹⁶¹ Louise Shelley, “Money Laundering into Real Estate,” in *Convergence: Illicit Networks and National Security in the Age of Globalization*, (Michael Miklaucic and Jacqueline Brewer eds., National Defense University Press 2013), p. 140 (noting how property purchased by money launderers that is left vacant may be allowed to decay so “criminal investors can subsequently buy neighboring properties at depressed costs, thereby increasing their territorial influence”); see also Final Report: Commission of Inquiry into Money Laundering in British Columbia, Cullen Commission (June 2022), p. 774, available at <https://cullencommission.ca/files/reports/CullenCommission-FinalReport-Full.pdf> (noting the ability of criminal actors to develop influence and power at a local level, such as in cases where a large real estate portfolio is owned in a small town or neighborhood).

FinCEN assesses that a regulatory requirement to ensure consistent reporting of non-financed real estate transfers made to legal entities and trusts on a nationwide basis would reduce law enforcement search costs for such information, thereby facilitating law enforcement and national security agency efforts to combat illicit activity. In this manner the proposed policy is expected to directly address the two main problems considered and in so doing create economic value.

2. Baseline and Affected Parties

To assess the anticipated regulatory impact of the proposed rule, FinCEN took several factors about the current state of the residential real estate market into consideration. This is consistent with established best practices and certain requirements¹⁶² that the expected economic effects of a proposed rule be measured against the status quo as a primary counterfactual. Among other factors, FinCEN’s economic analysis of regulatory impact considered the proposed rule in the context of existing regulatory requirements, relevant distinctive features of groups likely to be affected by the rule, and pertinent elements of current residential real estate market characteristics and common practices. Each of these elements is discussed in its respective subsection below.

a. Regulatory Baseline

While there are no specific Federal rules that would directly and fully duplicate, overlap, or conflict with the proposed rule,¹⁶³ there are nevertheless components of the proposed requirements that mirror, or are otherwise consistent with, reporting and procedural requirements of existing FinCEN rules and orders, as well as those of other agencies. To the extent that a person would have previous compliance experience with these elements of the regulatory baseline, FinCEN expects that some costs associated with the proposed rule would be lower because the incremental changes in behavior from current practices would be smaller. FinCEN reviews the most proximate components from these existing rules and orders in greater detail below.

i. Residential Real Estate GTOs

Under the Residential Real Estate GTOs, title insurance companies are required to report: “(i) The dollar

¹⁶² Office of Management and Budget, Circular A–4 (Nov. 9, 2023), available at <https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>.

¹⁶³ 5 U.S.C. 603(b)(5).

¹⁵⁶ See, e.g., Money Laundering in Real Estate, Conference Report by the Terrorism, Transnational Crime and Corruption Center at George Mason University (Mar. 25, 2018), available at tracc.gmu.edu/wp-content/uploads/2020/09/2018-MLRE-Report_0.pdf.

¹⁵⁷ “Anti Money Laundering and Economic Stability,” International Monetary Fund Finance & Development Magazine (Dec. 2018), availability at <https://www.imf.org/en/Publications/fandd/issues/2018/12/imf-anti-money-laundering-and-economic-stability-straight>.

¹⁵⁸ See, e.g., Final Report: Commission of Inquiry into Money Laundering in British Columbia, Cullen Commission (June 2022), p. 772, available at <https://cullencommission.ca/files/reports/CullenCommission-FinalReport-Full.pdf>. (highlighting structural and regulatory factors as incentives for using real estate to launder funds, including “minimal reporting of suspicious transactions . . . on the part of real estate professionals”), citing Transparency International, “Doors Wide Open: Corruption and Real Estate in Four Key Markets” (2017), pp. 24, available at <https://images.transparencycdn.org/images/2020-Report-Real-estate-data-Shining-a-light-on-the-corrupt.pdf>; Mohammed Ahmad Naheem, “Money Laundering and Illicit Flows from China—The Real Estate Problem,” *Journal of Money Laundering Control* (2017), p. 23, available at <https://www.emerald.com/insight/content/doi/10.1108/JMLC-08-2015-0030/full/html>.

¹⁵⁹ See Financial Action Task Force, Guidance for a Risk Based Approach: Real Estate Sector (July 2022), pp. 17, 29, available at <https://www.fatf-gafi.org/content/dam/fatf-gafi/guidance/RBA-Real-Estate-Sector.pdf.coredownload.pdf> (“[d]isparities with rules surrounding legal structures across countries means property can often be acquired abroad by shell companies or trusts based in secrecy jurisdictions, exacerbating the risk of money laundering.” International bodies, such as the FATF, have found that “[s]uccessful AML/CFT supervision of the real estate sector must contend with the obfuscation of true ownership provided by legal entities or arrangements[.]”).

amount of the transaction; (ii) the type of transaction; (iii) information identifying a party to the transaction, such as name, address, date of birth, and tax identification number; (iv) the role of a party in the transaction (*i.e.*, originator or beneficiary); and (v) the name, address, and contact information for the domestic financial institution or nonfinancial trade or business.”¹⁶⁴

As discussed above,¹⁶⁵ FinCEN recognizes that the Residential Real Estate GTOs collect beneficial ownership information on certain non-financed purchases of residential real property by legal entities that meet or exceed certain dollar thresholds in select geographic areas. However, the Residential Real Estate GTOs are narrow in that they are temporary, location-specific, and limited in the transactions they cover. The proposed rule is wider in scope of coverage and, if finalized, would collect additional useful and actionable information previously not available through the Residential Real Estate GTOs. As such, the proposed nationwide reporting framework for certain residential real estate transfers, if finalized, would replace the current Residential Real Estate GTOs.

Some evidence suggests that, despite the restricted scope of reporting persons under the existing Residential Real Estate GTOs to title insurance carriers only, certain additional categories of real estate professionals may already be familiar—and have experience—with gathering the currently required reportable information. For example, FinCEN observes that in some markets presently under a Residential Real Estate GTOs, realtors and escrow agents often assist Direct Title Insurance Carriers with their reporting obligations despite not being subject to any formal reporting requirements themselves. Some may even have multiple years’ worth of guidance and informational support by the regional or national trade association of which they are a member in how best to facilitate and enable compliance with existing FinCEN requirements. For instance, in 2021, the National Association of Realtors advised that while “[r]eal estate professionals do not have any affirmative duties under the Residential Real Estate GTOs,” such entities should nevertheless expect that “a title insurance company may request information from real estate professionals to help maintain its compliance with the Residential Real Estate GTOs. Real estate professionals are encouraged to cooperate and provide

information in their possession.”¹⁶⁶ Thus, the historical Residential Real Estate GTOs’ attempt to limit the definition of reporting persons to Direct Title Insurance Carriers does not seem to have completely forestalled the imposition of time, cost, and training burdens on other real estate transfer related entities. As such, the proposed cascade approach might not mark a complete departure from current practices and the related burdens of Residential Real Estate GTO requirements, as they may already in some ways be functionally applicable to multiple prospective reporting persons in the proposed cascade.

ii. BOI Reporting Rule

Furthermore, following the enactment of the CTA, beneficial ownership information of certain legal entities is required to be submitted to FinCEN. However, as set out in the preamble to this proposed rule, the information needed to ascertain money laundering risk in the residential real estate sector differs in key aspects from what will be collected under the CTA, and, accordingly, the information collected under this proposed rule differs from that collected under the CTA.¹⁶⁷

For example, FinCEN believes that a critical part of the proposed rule is that it would alert law enforcement to the fact that a real estate transfer vulnerable to a known money laundering typology has taken place. While beneficial ownership information collected under the CTA may be available, that information concerns the ownership composition of a given entity at a given point in time. As such reporting does not dynamically extend to include information on the market transactions of the beneficially owned legal entity, it would not alert law enforcement officials focused on reducing money laundering that any real estate transfer has been conducted, which includes those particularly vulnerable to money laundering such as non-financed transfers of residential property.

Furthermore, the scope of entities that are the focus of the real estate rule is broader than the CTA, as certain entities such as most types of trusts are not covered by the CTA. Because legal trusts generally do not have an obligation to

report beneficial ownership under the CTA, their incremental burden of compliance with the proposed Real Estate Report requirements may be moderately higher insofar as the activities of collecting, presenting, or certifying beneficial ownership information are less likely to have already been performed for other purposes.

iii. CDD Rule

The CDD Rule’s beneficial ownership requirement addressed a regulatory weakness that enabled persons looking to hide ill-gotten proceeds to potentially access the financial system anonymously. Among other things, covered financial institutions were required to identify and verify the identity of beneficial owners of legal entity customers, subject to certain exclusions and exemptions; beneficial ownership and identification therefore became a component of AML requirements.

FinCEN is also aware that financial institutions subject to the CDD Rule are required to collect some beneficial ownership information from legal entities that establish new accounts. However, those entities do not necessarily also own real estate and financial institutions are not required to file a report of that beneficial ownership information with FinCEN. In addition, the proposed rule covers non-financed transfers of residential real estate that do not involve financial institutions covered by the CDD Rule. The rule would also collect additional information relevant to the real estate transfers that is currently not collected under the CDD Rule.

iv. Other

In the course of current residential real estate transactions, some parties that under the proposed rule might be deemed “transferors” already prepare and report portions of the proposed requisite information to other regulators. For example, the IRS collects taxpayer information through Form 1099-S on seller-side proceeds from reportable real estate transfers for a broader scope of reportable real estate transactions than the proposed rule.¹⁶⁸ This information, however, is generally unavailable for one of the primary purposes intended by FinCEN’s proposed rule, as there are significant statutory limitations on the ability of the IRS to share such

¹⁶⁶ See National Association of Realtors, “Anti-Money Laundering Voluntary Guidelines for Real Estate Professionals” (Feb. 16, 2021), p. 3, available at <https://www.narfocus.com/billdatabase/clientfiles/172/4/1695.pdf>.

¹⁶⁷ See *supra* Section III.B, which provides a full discussion on the differences between the information collected for the CTA and the information collected under the proposed rule, both in terms of the depth of the information collected and the context in which it is collected.

¹⁶⁸ Reportable real estate for purposes of IRS Form 1099-S includes, for example, commercial and industrial buildings (without a residential component) and non-contingent interests in standing timber, which are not covered under the proposed rule.

¹⁶⁴ 85 FR 84104 (Dec. 23, 2020).

¹⁶⁵ See discussion of Residential Real Estate GTOs, *supra* Section II.B.3; see also Section III.A.

information with federal law enforcement or other federal agencies.¹⁶⁹ In addition to these statutory limitations on IRS disclosure of taxpayer information, details about the buyer's beneficial ownership (the focus of the proposed rule) largely fall outside the scope of transaction information reported on the Form 1099-S.

However, IRS Form 1099-S is nonetheless relevant to the proposed rule's regulatory baseline, given the process by which the filing may be prepared and submitted to the IRS. Similar to what is proposed for the Real Estate Report, the person responsible for filing the form IRS Form 1099-S can either be determined through a cascade of the various parties who may be involved in the closing or settlement process, or, alternatively, certain categories of the involved parties may enter into a written agreement at or before closing to designate who must file Form 1099-S for the transaction. The agreement must identify the designated person responsible for filing the form, but it is not necessary that all parties to the transaction, or that more than one party even, enter into the agreement.¹⁷⁰ The agreement must: (1) identify by name and address the person designated as responsible for filing; (2) include the names and addresses of each person entering into the agreement; (3) be signed and dated by all persons entering into the agreement; (4) include the names and addresses of the transferor and transferee; and (5) include the address and any other information necessary to identify the property.¹⁷¹ The proposed rule's designation agreement requires, and is limited to, the same five components that may be included in a designation agreement accompanying Form 1099-S. Therefore, the exercise of designation as well as the collection of information and signatures it involves, as contemplated by the proposed rule, may already occur in connection with certain transfers of residential real property and in these cases be leveraged at minimal additional expense.

¹⁶⁹ See generally 26 U.S.C. 6103 (covering confidentiality and disclosure of returns and return information).

¹⁷⁰ IRS, Instructions for Form 1099-S, available at <https://www.irs.gov/instructions/i1099s>; 26 CFR 1.6045-4(e).

¹⁷¹ *Id.*

b. Baseline of Affected Parties

i. Transferees

1. Legal Entities

According to a recent study¹⁷² that analyzed Ztrax data¹⁷³ covering 2,777 U.S. counties and over 39 million residential housing market transactions from 2015 to 2019, the proportion of average county-month non-financed residential real estate transactions by legal entities was approximately 11 percent during the five-year period analyzed. When the sample is divided into counties that, by 2019, were under Residential Real Estate GTOs versus those that were never under GTOs, the proportions of average county-month non-financed sales to total purchases are approximately 13.6 percent and 11.2 percent, respectively.

Legal entities that purchase residential real estate vary by size and complexity of beneficial ownership structure. FinCEN analysis of the 2018 RHFS data found that micro investors or small business landlords who owned 1–2 units owned 66 percent of all single family and multifamily structures with 2–4 units. Conversely, investors in the residential rental market who owned at least 1000 properties owned only 2 percent of single-family homes and multi-family structures.

2. Legal Trusts

The proposed rule would extend the scope of reportable transactions to include non-financed purchases of residential real property by legal trusts when such a trust falls within the definition of “transferee trust” and is not exempted.¹⁷⁴ Historically, residential real property purchases by transferee trusts have not been covered under the current Residential Real Estate GTOs and the entities themselves are typically¹⁷⁵ not subject to beneficial ownership reporting requirements under the CTA. Therefore, FinCEN expects that legal trusts would be more homogeneously newly affected by the proposed rule than legal entities,

¹⁷² See Matthew Collin, Florian Hollenbach, and David Szakonyi, “The impact of beneficial ownership transparency on illicit purchases of U.S. property,” Brookings Global Working Paper #170, (Mar. 2022), p. 14, available at <https://www.brookings.edu/wp-content/uploads/2022/03/Illicit-purchases-of-US-property.pdf>.

¹⁷³ Zillow, Transaction and Assessment Database (ZTRAX), available at <https://www.zillow.com/research/ztrax/>.

¹⁷⁴ See Section IV.B.2; see also *infra* proposed amendment 31 CFR 1031.230.

¹⁷⁵ FinCEN notes that while most trusts are not reporting companies under the BOI Reporting Rule, a reporting company would be required to report a beneficial owner that owned or controlled the reporting company through a trust.

discussed above, as a cohort of affected parties.¹⁷⁶

Establishing a baseline population of potentially affected transferee trusts based on the existing population of legal trusts is challenging for several reasons. These reasons include the general lack of comprehensive and aggregated data on the number,¹⁷⁷ value, usage, and holdings of trusts formed in the United States, which in turn is a result of heterogeneous registration and reporting requirements, including instances where neither requirement currently exists. Because domestic trusts are created and administered under state law, and states have broad authority in how they choose to regulate trusts, there is variation in both the proportion of potential transferee trusts that are currently required to register as trusts in their respective states as well as the amount of information a given legal trust is required to report to its state about the nature of its assets or its structural complexity. Thus, limited comparable information may be available at a nationwide level besides what is reported for federal tax purposes and what is available is unlikely to represent the full population of potentially affected parties that would meet the proposed definition of transferee trust if undertaking the non-financed purchase of residential real property.

International heterogeneity in registration and reporting requirements for foreign legal trusts creates similar difficulties in assessing the population of potentially affected parties that are not originally registered in the United States. Further complicating this assessment is the exogeneity and unpredictability of changes to foreign tax and other financial policies, which studies in other, related contexts have shown, generally affect foreign demand for real estate.¹⁷⁸

While it is difficult to know exactly how many existing legal trusts there are, and within that population, how many

¹⁷⁶ See Section VII.A.2.b.i.1.

¹⁷⁷ FinCEN notes that while the U.S. Census Bureau does produce annual statistics on the population of certain trusts (NAICS 525—Funds, Trusts, and Other Financial Vehicles), such trusts are unlikely to be affected by the proposed rule and thus their population size is not informative for this analysis.

¹⁷⁸ See, e.g., Cristian Badrinza and Tarun Ramadorai, “Home away from home? Foreign demand and London House prices,” *Journal of Financial Economics* 130 (3) (2018), pp. 532–555, available at <https://doi.org/10.1016/j.jfineco.2018.07.010>; see also Caitlan S. Gorbach and Benjamin J. Keys, “Global Capital and Local Assets: House Prices, Quantities, and Elasticities,” Technical Report, National Bureau of Economic Research (2020), available at <https://www.nber.org/papers/w27370>.

own residential real estate (as a potential indicator of what proportion of new trusts might have a view to purchase residential real property), there is nevertheless a consistency in the limited existing empirical evidence that would support a conjecture that proportionally few of the expected reportable transactions would be likely to involve a transferee trust. A recent study of U.S. single-property residential transactions that occurred between 2015 and 2019 identified a trust as the buyer in 3.3 percent of observed transfers. FinCEN also conducted additional analysis of publicly available data that might help to quantify the proportion of trust ownership in residential real estate. Based on the Department of Housing and Urban Development and Census Bureau's Rental Housing Finance Survey (RHFS), identifiable trusts accounted for approximately 2.5 percent of rental housing ownership and approximately 8.2 percent of non-natural person ownership of rental housing.¹⁷⁹

To the extent that trusts' current residential real property holdings are linear in the number of housing units and current holdings is a reliable proxy for future purchasing activity, FinCEN does not expect the proportion of non-financed residential real property transfers in which the transferee is a non-excepted legal trust to exceed 5 percent of potentially affected transactions. No further refinements to this upper-bound-like estimate, based on the number of existing trusts that may be affected, would be feasible without a number of additional assumptions about market behavior that FinCEN declines to impose in the absence of better/more data. The public is invited to provide such data, if available.

3. Excepted Transferees

Exceptions to the general definitions of transferee entities and transferee trusts apply to certain highly regulated entities and trusts that are subject to BSA program requirements or to other significant regulatory reporting requirements.

For example, PIVs that are investment companies and registered with the SEC under section 8 of the Investment Company Act of 1940 would be excepted, while unregistered PIVs engaging in reportable transfers would not. Unregistered PIVs would instead be required to provide the transaction's

reporting person with the proposed specified information, particularly including the required information regarding their beneficial owners. FinCEN analysis of costs below assumes that any such unregistered PIV stood up for a reportable transfer would generally have, or have low-cost access to, the proposed information necessary for filing the proposed Real Estate Reports. FinCEN expects that a PIV that is not registered with the SEC—which can have at maximum four investors whose ownership percent is or exceeds 25 percent (the threshold for the ownership prong of the beneficial ownership test for entities)—would likely either (1) be an extension of that large investor, or (2) have a general partner who actively solicited known large investors. In either case, the unregistered PIV is likely to have most of the beneficial ownership information that would be required to complete the proposed Real Estate Report and access to the beneficial owner(s) to request the additional components of required information not already at hand.

Operating companies subject to the Securities Exchange Act of 1934's current and periodic reporting requirements, including certain special purpose acquisition companies (SPACs) and issuers of penny-stock, would also be excepted transferees under the proposed rule. FinCEN notes that the percent ownership threshold for beneficial ownership for SEC regulatory purposes is considerably lower than as defined in the CTA and related Exchange Act beneficial ownership-related disclosure obligations usually apply to more control persons at such a registered operating company.¹⁸⁰ Additionally, disclosures about the acquisition of real estate, including material non-financed purchases of residential property, are already required in certain periodic reports filed with the SEC.¹⁸¹ Therefore, an incremental informational benefit from not excepting SEC-registered operating companies as transferees for the purposes of the proposed Real Estate Report reporting requirements may either not exist or, at best, be very low while the costs to operating companies of reporting and compliance with an additional federal regulatory agency are expected to be comparatively high.

ii. Reporting Entities

Because the proposed reporting cascade is ordered by function

performed, or service provided, rather than by defined occupations or categories of service providers,¹⁸² attribution of work to the capacity in which a person is primarily employed is necessarily imprecise.¹⁸³ To account for the need to map from services provided to entities providing such services as a prerequisite to estimating the number of potentially affected parties, FinCEN acknowledges, but abstracts from, the common observation that title agents and settlement agents are “often the same entity that performs two separate functions in a real estate transaction,” and that “the terms title agent and settlement agent are often used interchangeably.”¹⁸⁴ For purposes of the remaining RIA, FinCEN groups potential reporting persons by features of their primary occupation and treats them as functionally distinct members of the cascade.¹⁸⁵ In total, FinCEN estimates there may be up to approximately 172,753 reporting persons and 642,508 employees of those persons that could be affected by the proposed rule. Of this total, the distribution of potential reporting persons as identified by primary occupation¹⁸⁶ is settlement agents (3.6 percent of potential reporting persons, 9.8 percent of the potentially affected labor force), title insurance companies (0.5 percent, 6.6 percent), real estate escrow agencies (10.9 percent, 10.5

¹⁸² See description of reporting cascade, *supra* Section IV.D.1; see also proposed 31 CFR 1031.320(c)(1).

¹⁸³ Insofar as the various compliance burdens estimated below could be improved by either changes to the methodology or the sources of data incorporated, FinCEN is soliciting public input.

¹⁸⁴ See Nam D. Pham, “The Economic Contributions of the Land Title Industry to the U.S. Economy,” *ndp Consulting* (Nov. 2012), p. 6, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2921931. This study was included as an appendix to a 2012 American Land Title Association comment letter submitted to the Consumer Financial Protection Bureau (CFPB) on the Real Estate Settlement Procedures Act (RESPA).

¹⁸⁵ FinCEN's RIA assumes that the first three functions identified in the proposed waterfall (being listed as the closing or settlement agent, preparing the closing or settlement statement, and filing the deed or other instrument) would be performed, if at all, by a single person, such that there are five distinct members of the cascade.

¹⁸⁶ FinCEN notes that the capacity in which a reporting person facilitates a residential real property transfer may not always be in the capacity of their primary occupation. However, as analysis here relies on the U.S. Census Bureau's annual Statistics of U.S. Business Survey, which is organized by NAICS code, the following nominal primary occupations (NAICS codes) are used for grouping and counting purposes: Title Abstract and Settlement Offices (541191), Direct Title Insurance Carriers (524127), Other Activities Related to Real Estate (531390), Offices of Lawyers (541110), and Offices of Real Estate Agents and Brokers (531210).

¹⁷⁹ See U.S. Census Bureau, Rental Housing Finance Survey (2021), available at https://www.census.gov/data-tools/demo/rhfs/I/*/?s_tableName=TABLE2.

¹⁸⁰ See discussion of SEC-registered operating companies, *supra* Section IV.B.1.a.

¹⁸¹ See, e.g., U.S. Securities and Exchange Commission, Instructions to Item 2.01 on Form 8-K; see also 17 CFR 210.3–14.

percent), attorneys¹⁸⁷ (9.3 percent, 16.7 percent), and other real estate professionals¹⁸⁸ (75.5 percent, 56.4 percent). For purposes of cost estimates throughout the remaining analysis, FinCEN computed the following fully loaded average hourly wages by the respective primary occupation categories: settlement agents, \$70.33; title insurers, \$70.46; real estate escrow agencies, \$84.15; attorneys, \$88.89; and other real estate professionals, \$84.15.

c. Market Baseline

i. Reportable Transfers

The scope of residential real estate transactions that would be affected by the proposed rule is jointly defined by the (1) the nature of the property transferred, (2) the nature of the consideration proffered, and (3) the legal organization of the party to whom the property is transferred.¹⁸⁹ For purposes of identification, the defining attribute for the nature of the property is that it is principally designed or demonstrably intended to become, the residence of one to four families, including cooperatives and unimproved land.¹⁹⁰ Additionally, the property must be located in the United States as defined in the BSA implementing regulations, including U.S. territories.¹⁹¹ Transfers that would be deemed reportable exclude all transactions where the transferees receive any extension of credit from a financial institution subject to AML/SAR Reporting program requirements that is secured by the residential real property being transferred. Reportable transfers would also generally exclude transfers associated with an easement, death, divorce, or bankruptcy and transfers for which there is no reporting person. Because certain transfer characteristics that would cause a transfer to be

excluded are not consistently identified across sources of transfer data, FinCEN estimates of the number below may generally be considered an upper bound of the expected affected transactions.

FinCEN considered several different sources of information and a mosaic of piecewise informative statistics to inform its estimate of the reportable transaction baseline. When considering existing home sales, FinCEN reviewed the National Association of Realtors Confidence Index Survey data on all-cash residential home sales between October 2008 and April 2021. In this data, the upper bound of all-cash transactions for existing home sales over this period was 35 percent,¹⁹² which totaled to 7,500,000.¹⁹³ FinCEN also used data from the U.S. Census Bureau to review the number of new home sales between 1988–2022. FinCEN utilized peak and trough values for new home sales and percent of cash transactions—as a proxy for non-financed transactions—from the historical range provided by the Census Bureau.¹⁹⁴ In analysis of this data, FinCEN observed that the upper bound number of all-cash transactions for new home sales was 9.6 percent,¹⁹⁵ which totaled to 1,283,000 for the analysis.¹⁹⁶ Considering yet another source, FinCEN reviewed Redfin data covering a period between 2000 to 2022 on investor purchases of existing homes to consider as a proxy for legal entity and trust purchases.¹⁹⁷ This data would suggest an upper bound of approximately 20 percent.¹⁹⁸ However, Redfin investor purchase data is unlikely to capture all the legal entity and trust purchases that are covered under the proposed rule, is likely to include purchases by entities that would be exempt from the proposed rule, and only covers the purchase of

existing residential real estate (*i.e.*, non-new developments).

FinCEN additionally made attempts to factor in the rule's inclusion of U.S. territories by including the number of new and existing home sales in Puerto Rico in 2022 in the final estimate of total potentially reportable transfers.¹⁹⁹ In 2022, FinCEN identified 9,962 existing home sales and 953 new home sales in Puerto Rico. Added to the previous totals, this brought the total number of estimated existing and new home sales in the United States to 7,509,962 and 1,283,953, respectively.

To account for quit claims to LLCs with zero consideration—*i.e.*, real estate transfers that would not be captured in Census or home sales data—FinCEN reviewed various county deed databases to estimate the annual number of quit claims to LLCs for zero-dollar consideration in the United States. FinCEN reviewed deed data from the following U.S. County databases: Cook County, Illinois; Cuyahoga County, Ohio; Monroe County, Ohio; Anderson County, Texas; Dallas County, Texas; Arapahoe County, Colorado; Routt County, Colorado; Berrien County, Michigan; Roscommon County, Texas; Garland County, Arkansas. Counties were selected based upon the ability to: (i) search for quit claim deeds, (ii) search for deeds with zero-dollar consideration, (iii) conduct a keyword search that included “LLC” in the title of the grantee, and (iv) search within the 2022 calendar year. FinCEN notes that its attempt to create a representative sample was likely limited by its search query requirements and the limitations of county databases in terms of searchability. This analysis was conducted across 10 counties in 6 states and the results are included below in Table 1:²⁰⁰

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2022/. Note that “all-cash” is the term used by Redfin. FinCEN does not know how Redfin defines “all-cash.”

¹⁹⁸ There was a paucity of publicly available information regarding the legal entity and trust components of overall non-financed residential real estate transfers. The Redfin estimate, *supra* note 198, was limited to investor purchases of existing homes only, and therefore still contains gaps. Nonetheless, the Redfin estimate was the most recently available data and provided the highest bound estimate on the role of non-natural persons in residential real estate transfers based on publicly available data.

¹⁹⁹ See Lalaine C. Delmendo, “Puerto Rico Residential Real Estate Market Analysis 2023,” Global Property Guide (Apr. 11, 2023), available at <https://www.globalpropertyguide.com/Caribbean/Puerto-Rico/Price-History>.

²⁰⁰ Counties were selected based on the ability to search for the above criteria via each county's online database.

¹⁸⁷ The estimate of potentially affected attorneys is calculated as ten percent of the total SUBS population of Offices of Lawyers. This estimate is based on the average from FinCEN analysis of U.S. legal bar association membership, performed primarily at the state level, identifying the proportion of (state) bar members that are members of the organization's (state's) real estate bar association. FinCEN considers this proxy more likely to overestimate than underestimate the number of potentially affected attorneys because, while not all members of a real estate bar association actively facilitate real estate transfers each year, it was considered less likely that an attorney would, in a given year, facilitate real estate transfers in a way that would make them a candidate reporting person for purposes of the proposed rule when such an attorney had not previously indicated an interest in real estate specific practice (by electing to join a real estate bar).

¹⁸⁸ NAICS Code 531210 (Offices of Real Estate Agents and Brokers).

¹⁸⁹ See discussion of affected transferees, *supra* Section VII.A.2.b.i.

¹⁹⁰ See discussion, *supra* Section IV.A; see also proposed 31 CFR 1031.320(b).

¹⁹¹ 31 CFR 1010.100(h).

¹⁹² See National Association of Realtors, “All-Cash Sales are Rising Sharply Amid Intense Competition” (May 24, 2021), available at <https://www.nar.realtor/blogs/economists-outlook/all-cash-sales-are-rising-sharply-amid-intense-buyer-competition>.

¹⁹³ See Calculated Risk, “NAR: Existing-Home Sales Decreased to 5.61 million SAAR in April” (May 19, 2022), available at <https://www.calculatedriskblog.com/2022/05/nar-existing-home-sales-decreased-to.html>.

¹⁹⁴ See U.S. Census Bureau, “Houses Sold by Type of Financing,” available at https://census.gov/construction/nrs/xls/soldfinc_cust.xls.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ See Lily Katz and Sheharyar Bokhari, “Investors Are Buying Roughly Half as Many Homes as They Were a Year Ago,” Redfin News (Feb. 25, 2023), available at <https://www.redfin.com/news/investor-home-purchases-q4-2022/>.

Table 1: Deed Analysis

State	County	Quit Claims to LLCs with No Consideration	Total Deeds	Percentage
Illinois	Cook	3,069	139,428	2.20%
Ohio	Cuyahoga	1,676	57,492	2.92%
Texas	Dallas	185	123,689	0.15%
Colorado	Arapahoe	141	80,397	0.18%
Michigan	Berrien	96	7,762	1.24%
Ohio	Monroe	142	1,036	13.71%
Texas	Anderson	2	4,709	0.04%
Michigan	Roscommon	29	3,206	0.90%
Colorado	Routt	12	4,722	0.25%
Arkansas	Garland	6	9,220	0.07%
Totals:		5,358	431,661	1.24%

As a result, the total number of estimated quit claims to LLCs covered by the rule is approximately 110,389.

While these sources do not provide a complete picture of the potential number of reportable transfers in the United States, they are useful in providing an approximate range for estimation and highlight the fact that

the potential range of transfers each year is dependent on multiple potential factors and conditions. Overall, the sources FinCEN reviewed suggest that hundreds of thousands of transfers may be covered under the proposed rule.

FinCEN also estimates that annually anywhere between 5.23 million—6.98 million existing homes that have been

purchased would be exempt from the purview of the rule. Similarly, among new home sales, FinCEN estimates that annually a range of between 305 thousand—1.26 million transactions will be exempt (See Table 2 below).

Table 2: Transactions Exempted

Category	Exemption Estimates	
	<i>Lower Bound</i>	<i>Upper Bound</i>
Existing Home Sales exempted	5,230,313	6,984,265
New Home Sales exempted	305,848	1,259,231

FinCEN acknowledges the conditionality that likely exists between variables used in its analysis, but notes the limitations associated with publicly available data on non-financed, residential real estate purchases by legal entities and trusts. In the exercise above, FinCEN had to rely on independent estimates of specific characteristics (*i.e.*, non-financed, legal entity) to estimate the potential number of covered transactions and exempted transactions.

On the basis of available data, studies, and qualitative evidence, and in the absence of large, unforeseeable shocks to the U.S. residential housing market, FinCEN analysis suggests that the number of potentially reportable transfers would be between approximately 800,000 and 850,000 annually.

ii. Current Market Characteristics

FinCEN took certain potentially informative aspects of the current market for residential real property into consideration when forming its expectations about the anticipated economic impact of the proposed rule. Among other things, FinCEN considered trends in the observable rate of turnover in the stock of existing homes. Additionally, FinCEN reviewed recent studies and data from the academic literature estimating housing supply elasticities on previously developed versus newly developed land.

FinCEN also considered recent survey results of the residential real estate holdings of high-net-worth individuals and the proportion of survey respondents who self-reported the intent to purchase additional residential real estate in the coming year.

Further, FinCEN reviewed studies of trends in the financing and certain distributional characteristics of shared equity housing, which includes co-operatives that could be affected by the proposed rule.

iii. Current Market Practices

1. Settlement and Closing

FinCEN assessed the role of various persons in the real estate settlement and closing process to determine a quantifiable estimate of each profession or industry's overall participation in that process. Accordingly, FinCEN conducted research based on publicly available sources to assess the general participation rate of the different types of reporting persons in the proposed rule's cascade. As part of its analysis, FinCEN noted a recent blog post citing data from the ALTA that 80 percent of

homeowners purchase title insurance when buying a home.²⁰¹

To better understand the distribution of the other types of persons providing residential real property transfer services to the transactions that would be affected by the proposed rules, FinCEN utilized county deed database records to approximate a randomly selected and representative sample of residential real estate transfers across the United States.²⁰² FinCEN made efforts to collect deed data that reflected a representative, nation-wide sample, both in terms of the number and geographic dispersion of deeds, but acknowledge selection was nevertheless constrained in part by the feasibility to search by deed type, among other factors.²⁰³ To the extent that the same analysis would yield substantively different results if performed over a larger sample (with either more geographic locations, more observations per location, or both), the public is invited to share such data or the results of analysis based on such data.

The final analysis included 100 deeds, of which 97 involved at least one of the following potential reporting persons: (i) Title Abstract and Settlement Offices, (ii) Direct Title Insurance Carriers, or (iii) Offices of Lawyers. A candidate reporting person was deemed to be involved with the creation of the deed if either (i) a company or firm performing one of these functions was included on the deed or (ii) an individual performing or employed by a company or firm performing one of these functions was included on the deed. FinCEN assessed the distribution of alternative entities identified on the remaining deeds, categorizing by reporting person type. Based on this qualitative analysis, FinCEN tentatively anticipates that

²⁰¹ See American Land Title Association, Home Closing 101, "Why 20% of Homeowners May Not Sleep Tonight," (June 3, 2020), available at <https://www.homeclosing101.org/why-20-percent-of-homeowners-may-not-sleep-tonight/>.

²⁰² In total, FinCEN evaluated ten deeds from eleven different U.S. counties in 2022 (removing deeds that were deemed to be out of scope). The 11 counties selected for the purposes of this analysis included: Garland County, Arkansas; Routt County, Colorado; Sarasota County, Florida; Polk County, Georgia; Montgomery County, Maryland; Berrien County, Michigan; Middlesex County, New Jersey; Cuyahoga County, Ohio; Indiana County, Pennsylvania; Greenwood County, South Carolina; and Dallas County, Texas.

²⁰³ The process of searching deeds across different U.S. counties is challenging from a data perspective. For example, FinCEN's research found that, in some counties, deeds could only be searched in-person; FinCEN was therefore unable to include these counties in the potential sample. Furthermore, certain other deeds were deemed not relevant for the scope of the rule and hence were excluded.

approximately three percent of reportable transaction might have a reporting person other than a settlement agent, title insurer, or attorney.

2. Records Search

Currently, law enforcement searches a variety of state and commercial databases (that may or may not include beneficial ownership information), individual county record offices, and/or use subpoena authority to trace the suspected use of criminal proceeds in the non-financed purchase of residential real estate. Even after a significant investment of resources, the identities of the beneficial owners may not be readily ascertainable. This fragmented and limited approach can slow down and decrease the overall efficacy of investigations into money laundering through real estate. This was one reason that FinCEN introduced the Residential Real Estate GTOs, which law enforcement has reported have significantly expanded their ability to investigate this money laundering typology. At the same time, the Residential Real Estate GTOs had certain restrictions that limited its usefulness nationwide. The proposed rule builds on and is intended to replace the Residential Real Estate GTOs framework and creates reporting and recording requirements for specific residential real estate transfers that would apply nationwide.

3. Description of Proposed Requirements

a. Transactions

The proposed rule does not require residential real estate transfers to be reported if the transfer involves: (i) an extension of credit to the transferee that is secured by the transferred residential real property and is extended by a financial institution that has both an obligation to maintain an AML program and an obligation to report suspicious transactions under this chapter; (ii) a grant, transfer, or revocation of an easement; (iii) a transfer resulting from the death of an owner of residential real property; (iv) a transfer incident to divorce or dissolution of a marriage; (v) a transfer to a bankruptcy estate; or (vi) a transfer that does not involve a reporting person.

b. Reporting Persons

The proposed rule would require a reporting person, as determined by either the reporting cascade or as pursuant to a designation agreement,²⁰⁴ to complete and electronically file a

²⁰⁴ See discussion of designation agreement, *supra* Section IV.D.3.

Real Estate Report containing certain information about the beneficial ownership of the legal entity(ies) or trust(s) involved in the non-financed exchange of residential real property. To facilitate the reporting person's completion of the required report, the transferee engaged in the non-financed property transfer would need to provide a certified copy of their beneficial ownership information²⁰⁵ via a form or other attestation to the completeness and accuracy of the reported information.

c. Required Information

The proposed rule would require certain professionals or businesses to report to FinCEN information about the transferor and the transferee behind the residential real estate transfer. This would include information on the legal entity or trust, its beneficial owners, and payment information. The collected information would be maintained by FinCEN in an existing database accessible to authorized users.

3. Expected Economic Effects

This section describes the main economic effects FinCEN anticipates the various affected parties identified above²⁰⁶ may experience. Because the primary value of the proposed rule would be in the extent to which it is able to address or ameliorate the economic problems discussed under the RIA's broad economic considerations,²⁰⁷ the remainder of this section focuses primarily on the

estimates of reasonably anticipated, quantifiable costs to affected parties.²⁰⁸ FinCEN aggregate cost estimates suggest that first year costs will be between approximately \$267.3 million and \$476.2 million and that the current dollar value of the aggregate costs in subsequent years will be between approximately \$245.0 million and \$453.9 million annually. FinCEN also invites public comment on these estimates.

a. Costs to Entities in the Reporting Cascade

i. Training

FinCEN recognizes that the proposed rule would impose certain costs on businesses positioned to provide services to non-financed residential real property transfers even in the absence of direct participation in a specific covered transaction, including the costs of preparing informational material and training personnel about the proposed rule generally as well as certain firm-specific policies and procedures related to reporting, complying, and documenting compliance.

To estimate expected training costs, FinCEN adopted a parsimonious model similar, in certain respects, to the methodology used by FinCEN when publishing the RIA for the 2016 CDD Rule (CDD Rule RIA).²⁰⁹ Taking into consideration, however, that, unlike reporting entities under the CDD rule, only one group of the proposed rule's affected reporting persons has pre-existing experience with other FinCEN

reporting and compliance requirements, the estimates of anticipated training time here are revised upward from the CDD Rule RIA to 75 minutes for initial training and 30 minutes for annual refresher training. FinCEN's method of estimation assumes that an employee who has received initial training once will then subsequently take the annual refresher training each following year. This assumption contemplates that more than half of the original training would not be firm-specific and remains useful to the employee regardless of whether they remain with their initial employer or change jobs within the same industry. As in the CDD Rule RIA high estimate model, FinCEN estimates that two-thirds of untrained employees receive the initial (lengthier) training each year. However, because the initial training is assumed to provide transferrable human capital in this setting, turnover is not relevant to the assignment to initial training in periods following Year 1. Thus, in the revised model, FinCEN calculates annual training costs as the combination of the expected costs of providing two-thirds of the previously untrained workforce per industry²¹⁰ with initial (lengthier) training and all previously trained employees with the refresher (shorter) training. Time costs are proxied by an industry-specific fully loaded average wage rate per industry.

Table 3 below presents the corresponding per person estimated training costs by primary occupation without adjustment for wage growth.

Table 3: Training Costs

Estimated Per Person Training Costs		Initial Training		Refresher (Year 2+)	
<i>Primary Business Categories</i>	<i>Fully Loaded Hourly Wage</i>	<i>Time (hours)</i>	<i>Total</i>	<i>Time (hours)</i>	<i>Total (unadjusted)</i>
Title Abstract and Settlement Offices	\$70.33	1.25	\$87.91	0.5	\$35.16
Direct Title Insurance Carriers	\$84.15	1.25	\$105.18	0.5	\$42.07
Other Activities Related to Real Estate	\$70.46	1.25	\$88.07	0.5	\$35.23
Offices of Lawyers	\$88.89	1.25	\$111.11	0.5	\$44.45
Offices of Real Estate Agents and Brokers	\$70.46	1.25	\$88.07	0.5	\$35.23

²⁰⁵ See description of required transferee beneficial ownership information, *supra* Section IV.E.6.

²⁰⁶ See Section VII.A.2.b.

²⁰⁷ See Section VII.A.1.

²⁰⁸ See Section VII.A.2.b.

²⁰⁹ See 81 FR 29397 (May 11, 2016) (*codified at* 31 CFR 1010.230).

²¹⁰ As previously grouped by NAICS code, see *supra* Section VII.A.2.b.ii.

To model industry-specific hiring inflows in periods following Year 1, FinCEN converted the Bureau of Labor Statistics (BLS) projected 10-year cumulative employment growth rates for 2022–2032²¹¹ for the NAICS code mostly closely associated with a given industry available. Additionally, inflation data from the Federal Reserve Bank of St. Louis was utilized to estimate annual wage growth given the opportunity cost of training is assumed to be equivalent to the wage of employees.²¹² Utilizing these inputs, and summing costs across all industries expected to be affected, FinCEN estimates that the aggregate initial year training costs would be approximately \$44.3 million dollars and the undiscounted aggregate training costs in

²¹¹ U.S. Bureau of Labor Statistics, Employment Projections, “Employment by industry, occupation, and percent distribution, 2021 and projected 2031,” available at <https://data.bls.gov/projections/nationalMatrix?queryParams=541100&ioType=i> (reflects projections for the closest NAICS code, across all occupations, and not on a specific occupation code basis [legal services]); U.S. Bureau of Labor Statistics, Employment Projections, “Employment by industry, occupation, and percent distribution, 2021 and projected 2031,” available at <https://data.bls.gov/projections/nationalMatrix?queryParams=524120&ioType=i> (direct insurance [except life, health, and medical] carriers); U.S. Bureau of Labor Statistics, Employment Projections, “Employment by industry, occupation, and percent distribution, 2021 and projected 2031,” available at <https://data.bls.gov/projections/nationalMatrix?queryParams=531000&ioType=i> (real estate).

²¹² See Federal Reserve Bank of St. Louis, 10-Year Breakeven Inflation Rate (as of July 18, 2023), available at <https://fred.stlouisfed.org/series/T10YIE>.

each of the subsequent years would range between approximately \$20.2 and \$27.3 million.

ii. Reporting

The total costs associated with reporting a given non-financed property transaction will likely vary with the specific facts and circumstances of the transfer. For instance, the cost of the time needed to prepare and file a report could differ depending on which party in the cascade is the reporting person because parties receive different compensating wages. The costs associated with the time to determine who is the reporting person will also vary by the number of potential parties who may assume the role and thus might be parties to a designation agreement.

FinCEN estimates an average per-party cost to determine the reporting person of 30 (15) minutes for the party that assumes the role if a designation agreement is (not) required and 15 minutes each for all non-reporting parties (assuming each tier in the cascade corresponds to one reporting person). Therefore, the range of potential time costs associate with determining the reporting person is expected to be between 15 to 90 minutes.²¹³ Recently, FinCEN received updated information from parties

²¹³ This upper bound estimate is based on an assumption that, at maximum, five distinct functional roles could be concurrently provided to a reportable transfer. See *supra* note 186.

currently reporting under the Residential Real Estate GTO indicating that the previously estimated time cost of 20 minutes for that reporting requirement was less than half the average time expended per report in practice. Based on this feedback, the filing time burden FinCEN anticipates for the proposed rule accordingly incorporates a 45-minute estimate for the collection and reporting of the subset of Real Estate Report required information that is similar to information in reports filed under the Residential Real Estate GTOs, although FinCEN recognizes that certain transactions may require significantly more time.²¹⁴ Mindful of these outliers, FinCEN estimates an average 2 hour per reportable transaction time cost to collect and review transferee and transaction-specific reportable information and related documents, and an average 30 minute additional time cost to reporting.

Table 4 below presents FinCEN’s estimates of the various potential per-party per-transaction reporting costs associated with a preparing and filing the proposed Real Estate Report.

²¹⁴ At present, FinCEN is unable to assess the extent to which the underlying distribution of completion times exhibits skew or the extent to which current timing outliers may more accurately represent the associated burden unique to newly affected transactions. FinCEN is therefore requesting additional data via public comments in the event that such data exists and would materially alter the related expected burden estimates below.

Table 4: Transaction Reporting Costs

Estimated Per Transaction Reporting Costs		Non-Reporting Party		Reporting Party			
		Designation-Related		Designation-Related		Designation-Independent	
Primary Business Categories	Fully Loaded Hourly Wage	Time (hours)	Total	Time (hours)	Total	Time (hours)	Total
Title Abstract and Settlement Offices	\$70.33	0.25	\$17.58	0.25	\$17.58	2.75	\$193.40
Direct Title Insurance Carriers	\$84.15	0.25	\$21.04	0.25	\$21.04	2.75	\$231.40
Other Activities Related to Real Estate	\$70.46	0.25	\$17.61	0.25	\$17.61	2.75	\$193.76
Offices of Lawyers	\$88.89	0.25	\$22.22	0.25	\$22.22	2.75	\$244.45
Offices of Real Estate Agents and Brokers	\$70.46	0.25	\$17.61	0.25	\$17.61	2.75	\$193.76

Based on the range of expected reportable transactions and the wages associated with different persons in the potential reporting cascade, FinCEN anticipates that the proposed rule's reporting costs may be between approximately \$158.2 million²¹⁵ and \$314.2 million.²¹⁶

Because FinCEN expects reporting persons to be able to rely on technology previously purchased and already deployed in the ordinary course of business (namely, computers and access to the internet) to comply with the proposed reporting requirements, no line item of incremental expected IT costs has been ascribed to reporting.

iii. Recordkeeping

The proposed rule would impose recordkeeping requirements on reporting persons as well as, in certain cases, members of a given reportable transaction's cascade that are not the reporting person. The primary variation in expected recordkeeping costs would flow from the conditions under which the reporting person has assumed their

role. Additional variation in costs may result from differences in the dollar value assigned to the reporting person's time costs as a function of their primary occupation.²¹⁷

If the reporting person assumes the role as a function of their position in the proposed reporting cascade, this would imply that no meaningfully distinct person involved in the transfer provided the preceding service(s). In this case, the reporting person's recordkeeping requirements would be limited to the retention of compliance documents (such as the transferee's certification of beneficial ownership information) for a period of five years in a manner that preserves ready availability for inspection as authorized by law.²¹⁸ Recordkeeping costs would therefore include those associated with creating and/or collecting the necessary documents, storing the records in an accessible format, and securely disposing of the records after the required retention period has elapsed. FinCEN anticipates that over the full recordkeeping lifecycle, each reportable transaction would, on average, require one hour of the reporting person's time, as well as a record processing and maintenance cost of ten cents. Because

FinCEN expects that records will primarily be produced and recorded electronically and estimates its own processing and maintenance costs at ten cents per record, it has applied the same expected cost per reportable transaction to reporting persons.²¹⁹ On aggregate, this would result in recordkeeping costs between approximately \$56.3 million and \$75.6 million associated with one year's reportable transactions.

If the reporting person has instead assumed the role as the result of a designation agreement, the proposed rule would impose additional recordkeeping requirements on both the reporting person and at least one other member of the proposed reporting cascade. This is because the existence of a designation agreement implies the existence of one or more distinct alternative parties to the reportable transaction that provided a preceding service or services as described in the proposed cascade. While the proposed rule only stipulates that "the person who would otherwise be the reporting person but for the agreement" would also be anticipated to incur recordkeeping costs, FinCEN expects the minimum number of additional parties required to retain a readily accessible copy of the designation

²¹⁵ This estimate assumes the lowest number of cascade participants (1), the lowest number of estimated annual transfers (800,000), reported by the entity with the lowest estimated wage rate (\$70.33/hr.).

²¹⁶ This estimate assumes the maximum number of cascade participants (five (see note 186), each compensated at .25 times their respective average wage rate), the highest number of estimated annual transfers (850,000), reported by the entity with the highest estimated wage rate (\$89.88/hr.).

²¹⁷ See discussion of reporting entity hourly wage rates, *supra* Section VII.A.2.b.ii.

²¹⁸ See discussion of recordkeeping requirements, *supra* Section IV.G; see also proposed amendment 31 CFR 1031.320(l).

²¹⁹ This is based on the assumption that reporting persons may face comparable market rates for the same technological services. However, FinCEN invites the public to provide additional data on the market rates faced by potentially affected parties.

agreement for a five-year period would, in practice, depend on the number of alternative reporting parties servicing the transaction in a capacity that precedes the designated reporting person's in the proposed cascade, as it would otherwise be difficult to demonstrate the prerequisite sequence of conditions were met to establish the "but for" of the proposed requirement. Conservatively assuming that each service in the proposed cascade is provided by a separate party, this would impose an incremental recordkeeping cost on at least two parties per transaction and at most five.²²⁰ Because FinCEN estimates of reporting costs already assign the costs of preparing a designation agreement to the reporting person (when a transaction includes a

designation agreement), the incremental recordkeeping costs it estimates here pertain solely to the electronic dissemination, signing, and storage of the agreement. This is assigned an average time cost of five minutes per signing party to read and sign the designation agreement, as well as a ten-cent record processing and maintenance cost per transaction. Thus, designation agreement-specific recordkeeping costs are expected to include a time cost of 10–50 minutes (assuming one signing party per tier of the cascade) and \$0.20–\$0.50 per reportable transaction that involves a designation. This corresponds to expected annual aggregate costs ranging from approximately \$9.5 million²²¹ to \$28.6 million.²²² FinCEN notes that it assumes

that rational parties to a reportable transaction would not enter into a designation agreement if the expected cost of doing so, including compliance with the proposed recordkeeping requirements, were not elsewhere compensated in the form of efficiency gains or other offsetting cost savings associated with other components of compliance with the proposed rule, such as training or reporting costs. As such, the estimates provided here should only be taken to reflect a pro forma accounting cost.

Table 5 below presents FinCEN's estimates of the various potential per-party per-transaction costs associated with the proposed Real Estate Report recordkeeping requirements.

Table 5: Recordkeeping Costs Per Party

Estimated Per Transaction Recordkeeping Costs		Non-Reporting Party		Reporting Party			
		Designation-Related		Designation-Related		Designation-Independent	
Primary Business Categories	Fully Loaded Hourly Wage	Time (minutes)	Total*	Time (minutes)	Total*	Time (hours)	Total* (unadjusted)
Title Abstract and Settlement Offices	\$70.33	5	\$5.96	5	\$5.96	1	\$70.43
Direct Title Insurance Carriers	\$84.15	5	\$7.11	5	\$7.11	1	\$84.25
Other Activities Related to Real Estate	\$70.46	5	\$5.97	5	\$5.97	1	\$70.56
Offices of Lawyers	\$88.89	5	\$7.51	5	\$7.51	1	\$88.99
Offices of Real Estate Agents and Brokers	\$70.46	5	\$5.97	5	\$5.97	1	\$70.56

* Total Recordkeeping cost estimates include both labor (wages) and technology costs (\$0.10)

b. Government Costs

To implement the proposed rule, FinCEN expects to incur certain operating costs that would include approximately \$8.5 million in the first year and approximately \$7 million each year thereafter. These estimates include anticipated novel expenses related to

technological implementation,²²³ stakeholder outreach and informational support, compliance monitoring, and potential enforcement activities as well as certain incremental increases to pre-existing administrative and logistic expenses.

While such operating costs are not typically considered part of the general economic cost of a proposed rule, FinCEN acknowledges that this treatment implicitly assumes that resources commensurate with the novel operating costs exist. If this assumption does not hold, then operating costs

²²⁰ See *supra* note 186.

²²¹ This estimate assumes the lowest estimated number of annual transfers occurs and that the designation agreement is between only the two reporting persons with the lowest and second lowest hourly wage rate.

²²² This estimate assumes the highest estimated number of annual transfers occurs and that all members of the cascade (compensated at their respective average wage rates) are party to the designation agreement.

²²³ Technological implementation for a new reporting form contemplates expenses related to

development, operations, and maintenance of system infrastructure, including design, deployment, and support, such as a help desk. It includes an anticipated processing cost of \$0.10 per submitted Real Estate Report.

associated with a rule may impose certain economic costs on the public in the form of opportunity costs from the agency's forgone alternative activities and those activities' attendant benefits. Putting that into the context of this proposed rule, and benchmarking against FinCEN's actual appropriated budget for fiscal year 2022 (\$161 million),²²⁴ the corresponding opportunity cost would resemble forgoing approximately five percent of current activities annually.

4. Economic Consideration of Policy Alternatives

a. Proposed Requirements Without the Option To Designate

Instead of the rule as proposed, FinCEN could have required the reporting person to be determined strictly by the reporting cascade without an option to designate. Given the expectation that rational parties to a transaction would prefer to assign tasks to the party for whom it is least costly to complete, this alternative could only have been as cost effective as the proposed approach (which includes the option to designate) in the event that the reporting cascade would otherwise always assign requirements to the party with the lowest associated compliance costs. In all other cases, the alternative would be more costly. FinCEN therefore declined to propose a standalone reporting cascade.

b. Traditional SAR and AML Program Requirements

Instead of the proposed streamlined reporting requirement, FinCEN could have proposed to impose the full traditional SAR and AML program requirements on the various real estate professionals included in the proposed reporting cascade. While this would almost certainly lead to the production of significantly more reports, and hence, potentially more transaction-related information available to law enforcement, the costs accompanying this alternative would be commensurately more significant and would likely disproportionately burden small businesses. Such weighting of costs towards smaller entities could increase transaction costs associated with residential real property transactions both directly via program-related operational costs and indirectly via the potential anticompetitive effects of program costs.

c. Alternative Certification Requirements

Instead of allowing the transferee legal entity or trust to certify to the reporting person that the beneficial ownership information they have provided is accurate to the best of their knowledge, FinCEN could have required the reporting person to certify the transferee's beneficial ownership information. This alternative would likely be accompanied by a number of increased costs, including a potential need for longer, more detailed compliance training, lengthier time necessary to collect and review documents supporting the reported transferee beneficial ownership information required, and increased recordkeeping costs. There may also be costs associated with transactions that might not occur, if for example, a reporting person is unwilling or unable to certify the transferee's information. If certain reporting persons are better positioned to absorb the risks associated with certifying transferee beneficial ownership information, this could also have an anticompetitive effect. In this scenario, it is foreseeable that smaller businesses could be at a disadvantage.

B. Executive Orders 12866, 13563, and 14094

Executive Orders 12866, 13563, and 14094 (E.O. 12866 and its amendments) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. E.O. 13563 also recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify.²²⁵

This proposed rule has been designated a "significant regulatory action;" accordingly, it has been reviewed by the Office of Management and Budget (OMB).

C. Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the RFA²²⁶ requires the agency either to provide an initial regulatory flexibility analysis (IRFA) with a proposed rule or certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. Although this proposed rule might apply to a substantial number of small entities, it is nonetheless not expected to have a significant economic impact given that FinCEN has attempted to minimize the burden on reporting persons by streamlining the reporting requirements and providing for an option to designate the reporting person. Accordingly, FinCEN certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. The basis for doing so is discussed in further detail below.

1. Estimate of the Number of Small Entities to Whom the Proposed Rule Will Apply

As discussed above,²²⁷ the proposed rule would apply to a variety of individuals and employers in real estate-related businesses²²⁸ insofar as such persons facilitate specifically non-financed transfers of residential property.²²⁹ The extent to which the proposed rule would apply to a person or business is therefore contingent on the extent to which they provide one of the services enumerated in the proposed reporting cascade²³⁰ to a non-exempt,²³¹ non-financed²³² transfer of residential property²³³ to a transferee entity²³⁴ or transferee trust.²³⁵

Because the rule proposes to introduce a streamlined reporting

²²⁶ 5 U.S.C. 601 *et seq.*

²²⁷ See Section VII.2.b.ii.

²²⁸ FinCEN acknowledges that because non-profit organizations are not exempt as transferees, certain small non-profits may also be affected by the proposed rule if they engage in the non-financed transfer of residential property. However, because non-profit organizations are typically accustomed to preparing and maintaining governing documents and financial records for accountability purposes (*e.g.*, with donors, to maintain tax-status, or for state regulatory purposes), it is generally expected that the beneficial ownership information that would need to be collected and provided to a reporting person would be relatively inexpensive to repackage for purposes of compliance with the proposed rule.

²²⁹ The proposed rule would not impose the full traditional SAR and AML program requirements on such businesses. See Section VII.A.5.b.

²³⁰ See Section IV.D.1.

²³¹ See Section IV.C.2; see also Section IV.C.4; see also Section IV.C.5; see also Section VII.A.2.c.i.

²³² See Section IV.C.1.

²³³ See Section IV.A.1.

²³⁴ See Section IV.B.1; see also Section IV.B.3.

²³⁵ See Section IV.B.2.

²²⁴ FinCEN, Congressional Budget Justification and Annual Performance Plan and Report FY 2024 (2023), available at <https://home.treasury.gov/system/files/266/15.-FinCEN-FY-2024-CJ.pdf>.

²²⁵ Executive Order 13563, 76 FR 3821 (Jan. 21, 2011), section 1(c) ("Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity . . . and distributive impacts.")

requirement that is transaction-specific and tailored to a relatively small subset²³⁶ of residential property transfers, and because only one member of the proposed reporting cascade would be required to file the proposed Real Estate Report per reportable transfer, the estimates below of the total potential number of small entities to whom the rule would apply will necessarily exceed the number of small entities that in practice will likely be affected by the rule, possibly by an order of magnitude or more. As previously explained,²³⁷ the proposed obligation to file a Real Estate Report follows a cascade stratified by the services provided to each non-financed residential transfer uniquely, not the primary occupation of the person providing the service. Therefore, while each tier of the proposed reporting cascade has, for purposes of estimating the broadest extent of persons to whom the rule could apply,²³⁸ been mapped to a primary business category, this should not be misinterpreted as an expectation that each business in each enumerated primary business category provides the specific services to the specific transactions that would trigger a compliance requirement under the proposed rule. FinCEN does not currently have comprehensive or reliable data from which to more generally²³⁹ and accurately parse small

businesses that theoretically could, in the ordinary course of business, provide a cascade-identified service to a transfer deemed reportable from those small businesses that do so in practice, but welcomes public comments that would inform such an exercise.²⁴⁰

The number of small entities to whom the proposed rule would apply is additionally sensitive to both how firm size is determined and the vintage of data used for the estimates. As illustrated in the footnotes to Table 6 below, while the consensus across data sources and methodological approaches is that an upper bound of potentially affected small entities includes approximately 160,800 firms (by the following primary business classifications: approximately 6,300 Title and Settlement Agents, 800 Direct Title Insurance Carriers, 18,000 persons performing Other Activities Related to Real Estate, 15,700 Offices of Lawyers, and 120,000 Offices of Real Estate Agents and Brokers), the point estimates differ non-trivially by how ‘small’ is operationally defined, and do not do so unidirectionally²⁴¹ across methodologies and data sources. The differences between the smallest and

title insurer, or attorney, suggesting that in most transactions a person primarily employed in other activities related to real estate, a real estate agent or broker, and their businesses may be unlikely to become the reporting person on a reportable transfer and thereby be affected by the proposed rule. However, because that finding speaks to the proportion of transactions that involved services from categories of primary business and not the proportion of businesses that provide cascade-identified services to reportable transfers, FinCEN declines to make conclusive inferences from that study for this purpose of estimating the population of affected businesses.

²⁴⁰ See Section VII.F.

²⁴¹ Meaning that no method of operationalizing the term ‘small’ or vintage of data consistently yields either the smallest or the largest numerical value of the population estimate.

largest estimated values per industry group can lead to small business impact analyses that differ in anticipated magnitudes of effect by over 28,900 firms collectively, meaning that an incremental change of \$100 in cost per firm could vary in aggregate estimated impact on small businesses by almost \$3 million. Because estimates of aggregate economic effects can thus depend to such an extent on methodological choices rather than business fundamentals, FinCEN instead considered economic effects estimated and presented at a per-firm by primary business category level of analysis as more informative.

The following table (Table 6) further illustrates the extent to which an estimate of the population of potentially affected small entities depends on how the term ‘small’ is defined, as operationalized over the most recent vintages of data available from the Census Bureau,²⁴² but it can also be used to approximate potential aggregate economic effects as a function of the per-firm cost analysis below while allowing the reader greater flexibility to impose the assumptions about the extent to which various small businesses would be implicated by the proposed rule, as each deems most reasonable.

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²⁴² For estimates based on the number of employees, FinCEN used the 2021 SUSB Annual Data Tables by Establishment Industry. U.S. Census Bureau, 2021 SUSB Annual Data Tables by Establishment Industry (Nov. 27, 2023), available at <https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html>. For receipts data-based estimates, FinCEN used the 2017 SUSB Annual Data Tables by Establishment Industry. U.S. Census Bureau, 2017 SUSB Annual Data Tables by Establishment Industry (May 2021), available at <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

²³⁶ See Section VII.A.2.b.i.1; see also Section VII.A.2.C.i.

²³⁷ See description of services provided by cascade tier, *supra* Section IV.D.1; see also explanation of mapping services to primary occupation data, *supra* Section VII.A.2.b.ii.

²³⁸ Measured as all persons who by virtue of primary occupation could foreseeably provide at least one service identified in the cascade.

²³⁹ For example, in FinCEN’s deed analysis (see Section VII.A.2.c.iii.1), only three of one hundred transfers that would have been reportable under the proposed rule did not involve a settlement agent,

Table 6: Proportion of Potentially Affected Small Entities by Definition of ‘Small’

			Firms Deemed ‘Small’ as Defined by		
<i>Primary Business Categories</i>	<i>NAICS Code</i>	<i>Maximum Annual Receipts for ‘Small’ Designation^a</i>	<i><20 Employees in 2021^b</i>	<i><500 Employees in 2021</i>	<i>Average Receipts below SBA threshold in 2017^c</i>
Title Abstract and Settlement Offices	541191	\$19.5 million	90.89%	97.29%	99.24%
Direct Title Insurance Carriers	524127	\$47 million	90.05%	99.87%	95.35%
Other Activities Related to Real Estate	531390	\$19.5 million	97.00%	99.70%	99.09%
Offices of Lawyers	541110	\$15.5 million	95.45%	99.87%	99.32%
Offices of Real Estate Agents and Brokers	531210	\$15 million	98.85%	99.90%	99.64%

^a 13 CFR 121.201.

^b These estimates correspond to the following number of firms as reported in the SUSB 2021 data (<20, <500): Title and Abstract Settlement Offices, 6,023 and 6,571, respectively; Direct Title Insurance Carriers, 796 and 865, respectively; Other Activities Related to Real Estate, 18,185 and 18,692, respectively; Offices of Lawyers, 15,308 and 16,017, respectively; and Office of Real Estate Agents and Brokers, 128,951 and 130,331, respectively.

^c Data on firm receipts is only available in years that end in two or seven; to utilize SBA receipts thresholds, 2017 survey data is the most recent usable vintage. These estimates correspond to the following number of firms as reported in the SUSB 2017 data: Title Abstract and Settlement Offices (6,782), Direct Title Insurance Carriers (738), Other Activities Related to Real Estate (15,474), Offices of Lawyers (16,262), and Offices of Real Estates Agents and Brokers (106,461).

2. Expectations of Impact

At this time, it is unclear how individual small entities or categories of small entities may choose to respond to the proposed rule, as a broad range of potentially optimal behaviors and outcomes are possible. FinCEN has carefully considered the economic impact associated with the spectrum of possible scenarios a small entity might face and summarizes its expectations of economic impacts in the paragraphs below. To preliminarily clarify why certain costs are presented on a per-firm basis while others are presented per transaction, it is important to keep the distinction in mind between the anticipated costs of compliance, like training, that are independent of participation in reporting activity and those that are transaction-based, or conditional, on participation in a

reportable transfer, like reporting and recordkeeping. Further, and within transaction-based costs, there are costs incurred by the reporting person that are independent of a designation agreement, costs incurred by the reporting person only when a designation agreement exists, and costs incurred by non-reporting persons when a designation agreement exists.²⁴³

The table below (Table 7) presents FinCEN estimates of the average annual payroll costs per employee at each of the types of small entities to whom the proposed rule would apply. This data provides a benchmark against which the anticipated costs of the proposed rule can be compared. FinCEN believes that an assessment of economic impact relative to individual payroll expenses is more appropriate for the purposes of this exercise because an analysis alternatively based on business receipts

would need to rely upon the most recent SUSB that includes revenue data. That survey is approximately seven years old and predates the impacts of the COVID-19 pandemic on the residential real estate market, the market which is the specific domain to which the proposed rule would apply. Payroll data is available for more recent vintages of the survey and is therefore more likely to reflect the number, distribution, and labor costs of the businesses to whom the proposed rule would apply. Furthermore, because estimated costs have been presented at a per-employee and per-transaction level throughout the RIA, FinCEN expects that the individual business reading the analysis, and best apprised of its own annual revenues, should have the requisite pieces of information necessary to individually assess the potential impact relative to its own unique facts and circumstances.

²⁴³ See Section VII.A.4.a.

**Table 7: Average Annual Payroll Expense per Employee at Small Entity
by Primary Business**

			Average Payroll/Number of Employees by Operational Definition of ‘Small’		
Primary Business Categories	NAICS Code	Maximum Annual Receipts for ‘Small’ Designation ^a	<20 Employees (2021, unadjusted)	<500 Employees (2021, unadjusted)	Average Receipts below SBA threshold (2017, unadjusted)
Title Abstract and Settlement Offices	541191	\$19.5 million	\$56,759.15	\$63,006.04	\$57,719.33
Direct Title Insurance Carriers	524127	\$47 million	\$61,332.52	\$77,798.41	\$59,706.51
Other Activities Related to Real Estate	531390	\$19.5 million	\$75,867.45	\$83,902.18	\$94,179.03
Offices of Lawyers	541110	\$15.5 million	\$73,259.85	\$90,790.19	\$98,885.14
Offices of Real Estate Agents and Brokers	531210	\$15 million	\$59,335.71	\$61,692.48	\$61,693.20

^a 13 CFR 121.201.

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a. Scenario 1: Little to No Effect

Some small entities can reasonably be expected to experience little to no economic impact from the rule. The kinds of small entities that would face this scenario include both those unaffected because they *ex ante* do not participate in reportable transfers and those that ensure they do not *ex post*.

Among other examples, this would be the case for all small entities that, in the ordinary course of business, do not provide services to the non-financed transfers of residential property to which the proposed rule pertains. FinCEN notes that, at present, there is no comprehensive data regarding the distribution of cascade-identified services used in connection with the proposed reportable transfers that is organized by firm size of the service providers and their primary business categories. It is therefore not known if, for example, the majority of parties to the proposed reportable transfers have historically obtained services from

predominantly larger firms in a given industry. While some evidence on the market concentration of title insurers suggests this might be the case for their services in real estate transactions more generally,²⁴⁴ it is unclear how transferable that observation would be to non-financed transactions exclusively. In cases where a small business in one of the identified primary business categories does not participate in non-financed, non-exempt transfers of residential property to a transferee entity or transferee trust, the proposed rule would not apply, and therefore no costs associated with training, reporting, or recordkeeping would be incurred.

Alternatively, some small entities to whom the proposed rule would apply

²⁴⁴ A recent article indicated that the top ten title insurers in 2022 enjoyed an 88.4 percent market share. See American Land Title Association, ALTA Reports Full-Year, Q4 2022 Title Insurance Premium Volume (May 8, 2023), available at <https://www.prnewswire.com/news-releases/alta-reports-full-year-q4-2022-title-insurance-premium-volume-301817499.html>.

(based on the previous provision of services to transactions that would become reportable) might, in light of the reporting requirement, preemptively adopt a business policy of not providing services to non-financed residential property transfers or otherwise form arrangements to ensure they do not become the reporting person. This would allow them to similarly forgo the need to implement training programs or incur compliance costs related to reporting or recordkeeping to the same extent as those small businesses who had never previously facilitated the proposed newly reportable transfers. Admittedly, these strategies may not be entirely cost-free as certain firms may incur some costs in the form of forgone transactions. Additionally, there may also be some transaction costs to forming the kinds of alternative arrangements, external business agreements, or partnerships necessary to ensure reportable transfers remain substantially unaffected, as desired. In many cases, FinCEN contemplates that a small business may ensure

accordingly via relatively informal arrangements, such as verbally (or else, absent formal consideration), with longstanding providers of contemporaneous closing services to the types of residential property transactions that would otherwise require the small business to file a Real Estate Report under the proposed rule.

While such arrangements might be formed at the minimal cost of a short phone call or in the course of an informal conversation, all of which would be considered *de minimis* costs, other forms of agreement might be more costly to certain small businesses. FinCEN notes that in keeping with the general principle of Coase Theorem,²⁴⁵ nothing prevents potential private bargaining arrangements by which an otherwise obligated reporting person might transfer the bulk of their responsibilities via an *ex ante* agreement to compensate their respective counterparty's costs associated with a designation agreement,²⁴⁶ either via performance of the related documentation exercise or via financial consideration commensurate with the designation agreement-specific costs. A more detailed estimate of such costs is articulated in the scenario analysis that follows.

b. Scenario 2: Partial Effect

Other small entities may only be marginally affected. These kinds of small entities may include some that already have experience reporting under

the Residential Real Estate GTO to the extent that such title insurers qualify as 'small.'²⁴⁷ Such entities already have expended resources to establish a compliance infrastructure, and given the similarities between the requirements under the Residential Real Estate GTOs and the requirements that would be imposed under the proposed rule, some of those costs would not be replicated to comply with the proposed rule. Therefore, the economic impact of the proposed rule on such entities will likely be less than it would be for entities who are not currently subject to the Residential Real Estate GTOs. The category of marginally affected small entities would also include entities that are categorically unlikely to become the reporting person when participating in reportable transfers.

For example, small entities that facilitate a reportable transaction along with other members of the reporting cascade may, by the nature of the service they provide, always reside in a tier below other service-providing entities and/or because of being further removed from the details required for the proposed Real Estate Report, may be unlikely to be designated in place of higher tier cascade members. Similarly, the nature of the service they provide may make it less likely that a reportable transfer occurs in which their service is the only third-party service obtained. As such, the main costs incurred as a consequence of the proposed rule would be associated with training,²⁴⁸ which would still be necessary to ensure proper recordkeeping²⁴⁹ associated with designation agreements and preparedness for reporting²⁵⁰ in the rare

event either is required. FinCEN notes that, as proposed, no designation agreement with a lower-tier service provider is required if a higher-tier party to a transaction files the required Real Estate Report, and entities in tiers lower than the reporting person are not required to verify or document verification that the higher-tier party filed the report. Therefore, to the extent that a marginally affected small entity of the type described here incurs reporting²⁵¹ or recordkeeping costs,²⁵² it would only be in instances where the tiers above it were absent from a deal, in which case it may still have the ability to designate the reporting requirements if lower tier services are being provided by an additional party to the transaction.

For small entities whose primary costs burden will be associated with employee training, such costs would represent an increase in payroll expense of approximately 0.2 percent per trained employee (see Tables 8 and 9 below, derived from Tables 3 and 7 above). Such a change is not expected to be economically significant. FinCEN further notes that while its RIA incorporates estimates that are informed by the previous CDD model of how training is operationalized, the proposed rule itself is silent on the manner, format, and duration of training, and the proportion of a business's workforce that needs to be trained. Therefore, to the extent that a small business may effectively train a sufficient proportion of its workforce to the necessary degree of familiarity with the proposed rule's reporting requirements to ensure appropriate compliance at costs lower than FinCEN estimates, it is expected to do so at its discretion.

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see also discussion of reporting costs, *infra* Section VII.C.2.c and Table 10.

²⁵¹ *Id.*

²⁵² *Supra*, note 250.

²⁴⁵ See R.H. Coase, "The Problem of Social Cost," *The Journal of Law and Economics*, vol. 3 (Oct. 1960). While Coase Theorem traditionally pertains to the resolution of externality problems by private parties given an initial allocation of property rights, the principle is expected in this context to apply similarly to the assignment of the proposed reporting requirement (and related costs) between businesses servicing a reportable transfer given an original assignment of the reporting responsibility.

²⁴⁶ See discussion of designation agreement specific recordkeeping costs, *supra* Section VII.A.4.a.iii.

²⁴⁷ See Section II.B.3; see also Section VII.A.1.a.i.

²⁴⁸ See Table 3; see generally Section VII.A.4.a.i.

²⁴⁹ See Section VII.G; see also discussion of recordkeeping costs, *supra* Section VII.A.4.a.iii; see also discussion of recordkeeping costs, *infra* Section VII.C.2.c and Table 11.

²⁵⁰ See Section VII.E; see also discussion of expected reporting costs, *supra* Section VII.A.4.a.ii;

Table 8: Initial Training Costs as a Fraction of Payroll

Per Person Initial Training Costs as a Fraction of Individual Annual Payroll Expense			Average Payroll/Number of Employees		
			'Small' as Defined by		
Primary Employment	NAICS Code	Maximum Annual Receipts for 'Small' Designation	< 20 Employees (2021)	< 500 Employees (2021)	Average Receipts below SBA threshold ^a (2017)
Title Abstract and Settlement Offices	541191	\$ 19.5 million	0.15%	0.14%	0.15%
Direct Title Insurance Carriers	524127	\$ 47 million	0.17%	0.14%	0.18%
Other Activities Related to Real Estate	531390	\$ 19.5 million	0.12%	0.10%	0.09%
Offices of Lawyers	541110	\$ 15.5 million	0.15%	0.12%	0.11%
Offices of Real Estate Agents and Brokers	531210	\$ 15 million	0.15%	0.14%	0.14%

^a 13 CFR 121.201.**Table 9: Refresher Training Costs as a Fraction of Payroll**

Per Person Refresher Training Costs (Unadjusted) as a Fraction of Individual Annual Payroll Expense			Average Payroll/Number of Employees		
			'Small' as Defined by		
Primary Employment	NAICS Code	Maximum Annual Receipts for 'Small' Designation	< 20 Employees (2021, unadjusted)	< 500 Employees (2021, unadjusted)	Average Receipts below SBA threshold ^a (2017, unadjusted)
Title Abstract and Settlement Offices	541191	\$ 19.5 million	0.06%	0.06%	0.06%
Direct Title Insurance Carriers	524127	\$ 47 million	0.07%	0.05%	0.07%
Other Activities Related to Real Estate	531390	\$ 19.5 million	0.05%	0.04%	0.04%
Offices of Lawyers	541110	\$ 15.5 million	0.06%	0.05%	0.04%
Offices of Real Estate Agents and Brokers	531210	\$ 15 million	0.06%	0.06%	0.06%

^a 13 CFR 121.201.

c. Scenario 3: Full Effect

The small entities that would be most affected are those that would, as a consequence of the proposed rule, incur

the full reporting requirement with certainty.

This could occur because no other members of the proposed reporting cascade participate in a given reportable

transfer or because, when other cascade members participate in a reportable transfer, no designation agreement reassigns the reporting requirement away from the small entity. In this

scenario, the small entity would incur the full or near full expected costs associated with training, reporting, and recordkeeping.²⁵³ Tables 10 and 11

below indicated that this would introduce a cost comparable to an approximately 0.5 percent increase in average small entity annual payroll

expense for one employee per transaction.²⁵⁴

Table 10: Reporting Costs as a Fraction of Payroll

Per Transaction Reporting Costs as a Fraction of Individual Annual Payroll Expense			Average Payroll/Number of Employees		
			'Small' as Defined by		
Primary Employment			< 20 Employees (2021, unadjusted)	< 500 Employees (2021, unadjusted)	Average Receipts below SBA threshold ^a (2017, unadjusted)
Non-Reporting Party	Designation-Related	Title Abstract and Settlement Offices	0.03%	0.03%	0.03%
		Direct Title Insurance Carriers	0.03%	0.03%	0.04%
		Other Activities Related to Real Estate	0.02%	0.02%	0.02%
		Offices of Lawyers	0.03%	0.02%	0.02%
		Offices of Real Estate Agents and Brokers	0.03%	0.03%	0.03%
Reporting Party	Designation-Related	Title Abstract and Settlement Offices	0.03%	0.03%	0.03%
		Direct Title Insurance Carriers	0.03%	0.03%	0.04%
		Other Activities Related to Real Estate	0.02%	0.02%	0.02%
		Offices of Lawyers	0.03%	0.02%	0.02%
		Offices of Real Estate Agents and Brokers	0.03%	0.03%	0.03%
	Designation-Independent	Title Abstract and Settlement Offices	0.34%	0.31%	0.34%
		Direct Title Insurance Carriers	0.38%	0.30%	0.39%
		Other Activities Related to Real Estate	0.26%	0.23%	0.21%
		Offices of Lawyers	0.33%	0.27%	0.25%
		Offices of Real Estate Agents and Brokers	0.33%	0.31%	0.31%

^a 13 CFR 121.201.

²⁵³ In the event that the small entity is the reporting person because no other person described in the cascade is involved in the transfer, costs are reduced by the absence of additional time needed to determine the reporting person and the absence

of time associated with the preparation, circulation, and recordkeeping associated with a designation agreement.

²⁵⁴ FinCEN notes that because the proposed rule is intended to replace the current Residential Real

Estate GTOs reporting requirement, framing the expected economic impact in terms of cost increases may overstate the anticipated incremental burden of compliance, particularly for small direct title insurance carriers.

Table 11: Recordkeeping Costs as a Fraction of Payroll

Per Transaction Total Recordkeeping Costs as a Fraction of Individual Annual Payroll Expense			Average Payroll/Number of Employees		
			<i>'Small' as Defined by</i>		
<i>Primary Employment</i>			<i>< 20 Employees (2021, unadjusted)</i>	<i>< 500 Employees (2021, unadjusted)</i>	<i>Average Receipts below SBA threshold^a (2017, unadjusted)</i>
Non-Reporting Party	Designation-Related	Title Abstract and Settlement Offices	0.011%	0.009%	0.010%
		Direct Title Insurance Carriers	0.012%	0.009%	0.012%
		Other Activities Related to Real Estate	0.008%	0.007%	0.006%
		Offices of Lawyers	0.010%	0.008%	0.008%
		Offices of Real Estate Agents and Brokers	0.010%	0.010%	0.010%
Reporting Party	Designation-Related	Title Abstract and Settlement Offices	0.011%	0.009%	0.010%
		Direct Title Insurance Carriers	0.012%	0.009%	0.012%
		Other Activities Related to Real Estate	0.008%	0.007%	0.006%
		Offices of Lawyers	0.010%	0.008%	0.008%
		Offices of Real Estate Agents and Brokers	0.010%	0.010%	0.010%
	Designation-Independent	Title Abstract and Settlement Offices	0.12%	0.11%	0.12%
		Direct Title Insurance Carriers	0.14%	0.11%	0.14%
		Other Activities Related to Real Estate	0.09%	0.08%	0.07%
		Offices of Lawyers	0.12%	0.10%	0.09%
		Offices of Real Estate Agents and Brokers	0.12%	0.11%	0.11%

^a 13 CFR 121.201.

* Total Recordkeeping cost estimates include both labor (wages) and technology costs (\$0.10)

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Alternatively, a small entity, for reasons of its own, might adopt a business policy to always be the reporting person on reportable transactions. In this case it would incur the incremental additional costs associated with preparing²⁵⁵ and circulating a designation agreement²⁵⁶ whenever higher-tier parties to the transaction participate but its cost profile would otherwise resemble the other types of 'full effect' small entities. The economic impact does not appear to be significant in these cases, which would be expected to impose the highest costs.²⁵⁷

²⁵⁵ See description of designation agreement time costs, *supra* Section VII.A.4.a.ii.

²⁵⁶ See description of designation agreement time and technology costs, *supra* Section VII.A.4.a.iii; see also Table 8.

²⁵⁷ Because the RFA does not statutorily define "significant" the SBA has acknowledged that what

While the general consensus of this analysis across the potential scenarios that a small business could find itself in, as a consequence of the proposed rule, is that the related incremental costs are not likely to be economically significant, it may also be worth nothing that an economically significant cost generally need not imply that the economic impact on a given firm or

is "significant" will vary depending on the economics of the industry or sector to be regulated. The agency is in the best position to gauge the small entity impacts of its regulations." See Small Business Administration, How to Comply with the Regulatory Flexibility Act (updated Aug. 2017), page 18 available at <https://advocacy.sba.gov/wp-content/uploads/2019/06/How-to-Comply-with-the-RFA.pdf>. Nevertheless, it has suggested that one potentially appropriate measure of an economically significant impact is one that "exceeds 5 percent of the labor costs of the entities in the sector." *Id.* p 19. FinCEN analysis here identifies a maximum average per transaction cost of approximately 0.5 percent, which is a full order of magnitude smaller than the proposed SBA threshold.

industry would also be significant. While that could be the case, the former is not a sufficient condition for the latter.

Because a non-financed residential property transfer involving one or more potential reporting persons, unless exempt, must be reported, the parties between whom the ownership transfers may have relatively little bargaining power over the extent to which incremental costs related to the proposed rule are passed-through. Parties may have few viable alternatives to compensating the reporting person for its additional compliance-related services other than to conduct the transaction with no reporting persons involved in the transfer. This may be undesirable to the parties engaged in the transfer for a number of risk and/or convenience-related reasons that outweigh the marginal increase in transaction fees. As such, even in a

scenario under which small entities would face the highest incremental costs,²⁵⁸ it still may not be the case that the direct economic impact on these small entities will be significant.

3. Certification

Having considered the various possible outcomes (as grouped above by scenarios FinCEN anticipates as most likely) for small entities under the proposed reporting requirements, FinCEN certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. FinCEN invites comments from members of the public.

D. Unfunded Mandates Reform Act

Section 202 of the UMRA²⁵⁹ requires that an agency prepare a statement before promulgating a rule that may result in expenditure by state, local, and Tribal governments, or the private sector, in the aggregate, of \$177 million or more in any one year.²⁶⁰ Section 202 of the UMRA also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. FinCEN believes that the preceding assessment of impact²⁶¹ satisfies the UMRA's analytical requirements, but invites public comment on any additional factors that, if considered, would materially alter the conclusions of the RIA.

E. Paperwork Reduction Act

The new reporting requirements in this proposed rule are being submitted to OMB for review in accordance with the PRA.²⁶² Under the PRA, 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 control number assigned by OMB. Written comments and recommendations for the proposed collection can be submitted by visiting www.reginfo.gov/public/do/PRAMain. Find this document by selecting "Currently Under Review—Open for Public Comments" or by using the search function. Comments are welcome and must be received by April 16, 2024. In accordance with the requirements of the PRA and its implementing regulations, 5 CFR part 1320, the following details concerning the collections of information are presented to assist those persons wishing to comment.

Reporting and Recordkeeping Requirements: The provisions in this proposed rule pertaining to the collection of information can be found in paragraph (a) of proposed 31 CFR 1031.320. The information that would be required to be reported by the proposed rule would be used by the U.S. Government to monitor and investigate money laundering in the U.S. residential real estate sector. The information required to be maintained by the proposed will be used by federal agencies to verify compliance by reporting persons with the provisions of the proposed rule. The collection of information is mandatory.

OMB Control Numbers: 1506–XXX.

Frequency: As required.

Description of Affected Public:

Residential Real Estate Settlement Agents, Title Insurance Carriers, Escrow Service Providers, Other Real Estate Professionals.

Estimated Number of Responses: 850,000²⁶³

Estimated Total Annual Reporting and Recordkeeping Burden: 4,604,167 burden hours²⁶⁴

Estimated Total Annual Reporting and Recordkeeping Cost: \$396,610,297.74²⁶⁵

General Request for Comments under the Paperwork Reduction Act: Comments submitted in response to this notice will be summarized and included in a request for OMB approval. All

comments will become a matter of public record. Comments are invited on the following categories: (a) whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on reporting persons, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

F. Additional Requests for Comment

1. In addition, FinCEN generally invites comment on the accuracy of FinCEN's regulatory analysis. FinCEN specifically requests comments—including data or studies—that provide additional insight on the following: What would be the short-term costs, burdens, and benefits associated with using a new reporting form to file the proposed information? The long term? What would be the costs, burdens, and benefits associated with collecting and storing the information detailed in this NPRM?

2. Would FinCEN's proposed regulatory requirements be integrated into current compliance programs in ways that are significantly more (or less) costly than anticipated in the RIA? How much time would be needed to successfully integrate them into current systems and procedures?

3. Would reporting persons and their employers integrate implementation costs into their existing budgets in ways that substantially differ from the expectations described in the RIA? If so, how might this affect the reliability or accuracy of the estimated costs?

4. Is FinCEN correct in assuming that, in a single reportable real estate transaction, only one business would perform any of the functions described in the first three tiers of the reporting cascade? If not, please provide details about, or examples of instances where, multiple parties with functions described in the first three tiers of the cascade would participate in a single transaction. If multiple parties do participate, would this result in an impact on the burden of compliance with the rule?

5. Of the affected parties identified in this analysis, would certain nonfinancial trades or businesses incur higher costs compared to others under this proposed rule? Why?

²⁵⁸ For example, the full costs of newly implementing a training program, filing the proposed Real Estate Report (potentially on that includes a designation agreement), and complying with the proposed recordkeeping requirements.

²⁵⁹ See 2 U.S.C. 1532(a).

²⁶⁰ The U.S. Bureau of Economic Analysis reported the annual value of the gross domestic product (GDP) deflator in 1995 (the year in which UMRA was enacted) as 71.823; and in 2022 as 127.215. See U.S. Bureau of Economic Analysis, "Implicit Price Deflators for Gross Domestic Product," Table 1.1.9, available at <https://apps.bea.gov/iTable/?reqid=19&step=2&isuri=1&categories=survey%23eyJhcHBpZC16MTksInNoZXZljbMSWYLDMS10sImRh dGEiOlthIkNhdGVnb3JpZXMiLCJTdXJ2ZXkiXSxbIk5JUEFVGfVGVibGVfTGZldC1sJjEz10sWyJGaXJzdF9ZZWYlIiwMTk5NSJdLFsiTGZzdF9ZZWYlIiwMjAyMSJdLFsiU2NhbGU iLC1w10sWyJ2ZXJpZXMiLCJBI1dfQ>. Thus, the inflation adjusted estimate for \$100 million is 127.215 divided by 71.823 and then multiplied by 100, or \$177 million.

²⁶¹ See Section VII.A.5; see generally Section VII.A.

²⁶² See 44 U.S.C. 3506(c)(2)(A).

²⁶³ This estimate represents the upper bound estimate of reportable transfers per year as described in greater detail above in Section VII.A.2.c.i.

²⁶⁴ This estimate includes the upper bound estimates of the time burden of compliance, as described in greater detail above, with the proposed reporting and recordkeeping requirements. See Section VII.A.4.a.ii; Section VII.A.4.a.iii.

²⁶⁵ This estimate includes the upper bound estimates of the wage and technology costs of compliance, as described in greater detail above, with the proposed reporting and recordkeeping requirements. See Section VII.A.4.a.ii; Section VII.A.4.a.iii.

6. Please detail any aspects of the proposed rule that may cause a business to operate at a competitive disadvantage compared to any business that offers similar services but would be outside the scope of the proposed rule.

7. To what extent are the services identified in the proposed reporting cascade likely to be primarily provided by small businesses?

8. To what extent might the costs of compliance with the proposed rule dissuade certain small businesses from providing services to reportable transfers? How large is the economic value of such potentially foregone transactions to small businesses? If possible, please provide data that would enable the quantification of these costs.

9. Please detail any aspects of the proposed rule that may cause a small business to operate at a competitive disadvantage compared to other businesses that offers similar services.

10. To what extent might the parties who would be reporting persons under the proposed rule be able to pass the costs of compliance on to downstream customers/clients? Are there concerns about such an allocation of the economic burden of compliance?

11. To the extent that services in the proposed reporting cascade tiers are currently ordered such that a small business would precede a larger business, are there any economic costs to designation or significant transaction frictions that would prevent reassigning the obligation in cases where the larger business is better positioned to absorb compliance costs?

List of Subjects in 31 CFR Part 1031

Administrative practice and procedure, Aliens, Authority delegations (Government agencies), Bankruptcy, Banks and banking, Brokers, Buildings and facilities, Business and industry, Condominiums, Cooperatives, Currency, Citizenship and naturalization, Electronic filing, Estates, Fair housing, Federal home loan banks, Federal savings associations, Federal-States relations, Foreign investments in U.S., Foreign persons, Foundations, Holding companies, Home improvement, Homesteads, Housing, Indian—law, Indians, Indians—tribal government, Insurance companies, Investment advisers, Investment companies, Investigations, Law enforcement, Lawyers, Legal services, Low and moderate income housing, Mortgage insurances, Mortgages, Penalties, Privacy, Real property acquisition, Reporting and recordkeeping requirements, Small businesses, Securities, Taxes, Terrorism, Time, Trusts and trustees, Zoning.

Authority and Issuance

■ For the reasons set forth in the preamble, chapter X of title 31 of the Code of Federal Regulations is proposed to be amended by adding part 1031 to read as follows:

PART 1031—RULES FOR PERSONS INVOLVED IN REAL ESTATE CLOSINGS AND SETTLEMENTS

Subparts A–B [Reserved]

Subpart C—Reports Required To Be Made by Persons Involved in Real Estate Closings and Settlements

Sec.

1031.320 Reports of residential real property transfers.

1031.321 [Reserved]

Authority: 12 U.S.C. 1829b, 1951–1959; 31 U.S.C. 5311–5314, 5316–5336; title III, sec. 314 Pub. L. 107–56, 115 Stat. 307; sec. 701 Pub. L. 114–74, 129 Stat. 599; sec. 6403, Pub. L. 116–283, 134 Stat. 3388.

Subparts A–B [Reserved]

Subpart C—Reports Required To Be Made by Persons Involved in Real Estate Closings and Settlements

§ 1031.320 Reports of residential real property transfers.

(a) *General.* A residential real property transfer as defined in paragraph (b) of this section (“reportable transfer”) shall be reported to FinCEN by the reporting person identified in paragraph (c) of this section. The report shall include the information described in paragraphs (d) through (i) of this section. Terms not defined in paragraph (j) of this section are defined in 31 CFR 1010.100. The report required by this section shall be filed in the form and manner, and at the time, specified in paragraph (k) of this section. Records shall be retained as specified in paragraph (l) of this section and are not confidential as specified in paragraph (m) of this section.

(b) *Reportable transfer.* (1) Except as set forth in paragraph (b)(2) of this section, a reportable transfer is a transfer to a transferee entity or transferee trust of an ownership interest in:

(i) Real property located in the United States containing a structure designed principally for occupancy by one to four families;

(ii) Vacant or unimproved land located in the United States zoned, or for which a permit has been issued, for the construction of a structure designed principally for occupancy by one to four families; or

(iii) Shares in a cooperative housing corporation where such transfer does

not involve an extension of credit to all transferees that is:

(A) Secured by the transferred residential real property; and

(B) Extended by a financial institution that has both an obligation to maintain an anti-money laundering program and an obligation to report suspicious transactions under this chapter.

(2) A reportable transfer does not include a:

(i) Grant, transfer, or revocation of an easement;

(ii) Transfer resulting from the death of an owner of residential real property;

(iii) Transfer incident to divorce or dissolution of a marriage;

(iv) Transfer to a bankruptcy estate; or

(v) Transfer for which there is no reporting person.

(c) *Determination of reporting person.*

(1) Except as set forth in paragraphs (c)(2) and (3) of this section, the reporting person for a reportable transfer is the person engaged within the United States as a business in the provision of real estate closing and settlement services that is:

(i) The person listed as the closing or settlement agent on the closing or settlement statement for the transfer;

(ii) If no person is described in paragraph (c)(1)(i) of this section, the person that prepares the closing or settlement statement for the transfer;

(iii) If no person is described in paragraph (c)(1)(i) or (ii) of this section, the person that files with the recordation office the deed or other instrument that transfers ownership of the residential real property;

(iv) If no person described in paragraph (c)(1)(i), (ii), or (iii) of this section is involved in the transfer, then the person that underwrites an owner's title insurance policy for the transferee with respect to the transferred residential real property, such as a title insurance company;

(v) If no person described in paragraph (c)(1)(i), (ii), (iii), or (iv) of this section is involved in the transfer, then the person that disburses in any form, including from an escrow account, trust account, or lawyers' trust account, the greatest amount of funds in connection with the residential real property transfer;

(vi) If no person described in paragraph (c)(1)(i), (ii), (iii), (iv), or (v) of this section is involved in the transfer, then the person that provides an evaluation of the status of the title; or

(vii) If no person described in paragraph (c)(1)(i), (ii), (iii), (iv), (v), or (vi) of this section is involved in the transfer, then the person that prepares the deed or, if no deed is involved, any

other legal instrument that transfers ownership of the residential real property.

(2) *Employees, agents, and partners.* If an employee, agent, or partner acting within the scope of such individual's employment, agency, or partnership would be the reporting person as determined in paragraph (c)(1) of this section, then the individual's employer, principal, or partnership is deemed to be the reporting person.

(3) *Designation agreement.* (i) The reporting person described in paragraph (c)(1) of this section may agree with any other person described in paragraph (c)(1) to designate such other person as the reporting person with respect to the reportable transfer. The person designated by such agreement shall be the reporting person with respect to the transfer.

(ii) A designation agreement shall be in writing, and shall include:

(A) The date of the agreement;

(B) The name and address of the transferor;

(C) The name and address of the transferee entity or transferee trust;

(D) Information described in in paragraph (g) identifying transferred residential real property;

(E) The name and address of the person designated through the agreement as the reporting person with respect to the transfer; and

(F) The name and address of all other parties to the agreement.

(d) *Information concerning the reporting person.* The reporting person shall report:

(1) The full legal name of the reporting person;

(2) The category of reporting person, as determined in paragraph (c) of this section; and

(3) The street address that is the reporting person's principal place of business in the United States.

(e) *Information concerning the transferee—(1) Transferee entities.* For each transferee entity involved in a reportable transfer, the reporting person shall report:

(i) The following information for the transferee entity:

(A) Full legal name;

(B) Trade name or "doing business as" name, if any;

(C) Complete current address consisting of:

(1) The street address that is the transferee entity's principal place of business; and

(2) If such principal place of business is not in the United States, the street address of the primary location in the United States where the transferee entity conducts business, if any; and

(D) Unique identifying number consisting of:

(1) The Internal Revenue Service Taxpayer Identification Number (IRS TIN) of the transferee entity;

(2) If the transferee entity has not been issued an IRS TIN, a tax identification number for the transferee entity that was issued by a foreign jurisdiction and the name of such jurisdiction; or

(3) If the transferee entity has not been issued an IRS TIN or a foreign tax identification number, an entity registration number issued by a foreign jurisdiction and the name of such jurisdiction;

(ii) The following information for each beneficial owner of the transferee entity:

(A) Full legal name;

(B) Date of birth;

(C) Complete current residential street address;

(D) Citizenship; and

(E) Unique identifying number

consisting of:

(1) An IRS TIN; or

(2) Where an IRS TIN has not been issued:

(i) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(ii) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government; and

(iii) The following information for each signing individual, if any:

(A) Full legal name;

(B) Date of birth;

(C) Complete current residential street address;

(D) Unique identifying number consisting of:

(1) An IRS TIN; or

(2) Where an IRS TIN has not been issued:

(i) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(ii) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government to the individual;

(E) Description of the capacity in which the individual is authorized to act as the signing individual; and

(F) If the signing individual is acting in that capacity as an employee, agent, or partner, the name of the individual's employer, principal, or partnership.

(2) *Transferee trusts.* For each transferee trust in a reportable transfer, the reporting person shall report:

(i) The following information for the transferee trust:

(A) Full legal name, such as the full title of the agreement establishing the transferee trust;

(B) Date the trust instrument was executed;

(C) The street address that is the trust's place of administration;

(D) Unique identifying number, if any, consisting of:

(1) IRS TIN; or

(2) Where an IRS TIN has not been issued, a tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; and

(E) Whether the transferee trust is revocable;

(ii) The following information for each trustee that is a legal entity:

(A) Full legal name;

(B) Trade name or "doing business as" name, if any;

(C) Complete current address consisting of:

(1) The street address that is the trustee's principal place of business; and

(2) If such principal place of business is not in the United States, the street address of the primary location in the United States where the trustee conducts business, if any;

(D) Name and business address of the trust officer assigned to the transferee trust; and

(E) Unique identifying number consisting of:

(1) The IRS TIN of the trustee;

(2) In the case that a trustee has not been issued an IRS TIN, a tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(3) In the case that a trustee has not been issued an IRS TIN or a foreign tax identification number, an entity registration number issued by a foreign jurisdiction and the name of such jurisdiction; and

(F) For purposes of this section, an individual trustee of the transferee trust is considered to be a beneficial owner of the trust. As such, information on individual trustees must be reported in accordance with the requirements set forth in paragraph (e)(2)(iii) of this section;

(iii) The following information for each beneficial owner of the transferee trust:

(A) Full legal name;

(B) Date of birth;

(C) Complete current residential street address;

(D) Citizenship;

(E) Unique identifying number consisting of:

(1) An IRS TIN; or

(2) Where an IRS TIN has not been issued:

(i) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(ii) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government; and

(F) The category of beneficial owner, as determined in paragraph (j)(1)(ii) of this section; and

(iv) The following information for each signing individual, if any:

(A) Full legal name;

(B) Date of birth;

(C) Complete current residential street address;

(D) Unique identifying number consisting of:

(1) An IRS TIN; or

(2) Where an IRS TIN has not been issued:

(i) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(ii) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government to the individual;

(E) Description of the capacity in which the individual is authorized to act as the signing individual; and

(F) If the signing individual is acting in that capacity as an employee, agent, or partner, the name of the individual's employer, principal, or partnership.

(3) *Collection of beneficial ownership information from transferees.* The reporting person may collect the information described in paragraphs (e)(1)(ii) and (e)(2)(iii) of this section from the transferee or a person representing the transferee in the reportable transfer, provided the transferee or their representative certifies in writing, to the best of their knowledge, the accuracy of the information.

(f) *Information concerning the transferor.* For each transferor involved in a reportable transfer, the reporting person shall report:

(1) The following information for a transferor who is an individual:

(i) Full legal name;

(ii) Date of birth;

(iii) Complete current residential street address; and

(iv) Unique identifying number consisting of:

(A) An IRS TIN; or

(B) Where an IRS TIN has not been issued:

(1) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(2) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government to the individual;

(2) The following information for a transferor that is a legal entity:

(i) Full legal name;

(ii) Trade name or “doing business as” name, if any;

(iii) Complete current address consisting of:

(A) The street address that is the legal entity's principal place of business; and

(B) If the principal place of business is not in the United States, the street address of the primary location in the United States where the legal entity conducts business, if any; and

(iv) Unique identifying number consisting of:

(A) An IRS TIN;

(B) In the case that the legal entity has not been issued an IRS TIN, a tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(C) In the case that the legal entity has not been issued an IRS TIN or a foreign tax identification number, an entity registration number issued by a foreign jurisdiction and the name of such jurisdiction; and

(3) The following information for a transferor that is a trust:

(i) Full legal name, such as the full title of the agreement establishing the trust;

(ii) Date the trust instrument was executed;

(iii) Unique identifying number, if any, consisting of:

(A) IRS TIN; or

(B) Where an IRS TIN has not been issued, a tax identification number issued by a foreign jurisdiction and the name of such jurisdiction;

(iv) For each individual who is a trustee of the trust:

(A) Full legal name;

(B) Current residential street address; and

(C) Unique identifying number consisting of:

(1) An IRS TIN; or

(2) Where an IRS TIN has not been issued:

(i) A tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(ii) The unique identifying number and the issuing jurisdiction from a non-expired passport issued by a foreign government; and

(v) For each legal entity that is a trustee of the trust:

(A) Full legal name;

(B) Trade name or “doing business as” name, if any;

(C) Complete current address consisting of:

(1) The street address that is the legal entity's principal place of business; and

(2) If the principal place of business is not in the United States, the street address of the primary location in the United States where the legal entity conducts business, if any; and

(D) Unique identifying number consisting of:

(1) An IRS TIN;

(2) In the case that the legal entity has not been issued an IRS TIN, a tax identification number issued by a foreign jurisdiction and the name of such jurisdiction; or

(3) In the case that the legal entity has not been issued an IRS TIN or a foreign tax identification number, an entity registration number issued by a foreign jurisdiction and the name of such jurisdiction.

(g) *Information concerning the residential real property.* The reporting person shall report the street address, if any, and the legal description, such as the section, lot, and block, of each residential real property that is the subject of the reportable transfer.

(h) *Information concerning payments.*

(1) The reporting person shall report the following information concerning each payment, other than a payment disbursed from an escrow or trust account held by a transferee entity or transferee trust, that is made by or on behalf of the transferee entity or transferee trust regarding a reportable transfer:

(i) The amount of the payment, consisting of the total consideration paid by the transferee entity or transferee trust;

(ii) The method by which the payment was made;

(iii) If the payment was paid from an account held at a financial institution, the name of the financial institution and the account number; and

(iv) The name of the payor on any wire, check, or other type of payment if the payor is not the transferee entity or transferee trust.

(2) The reporting person shall report the total consideration paid or to be paid by all transferees regarding the reportable transfer.

(i) *Information concerning hard money, private, and other similar loans.* The reporting person shall report whether the reportable transfer involved credit extended by a person that is not a financial institution with an obligation to maintain an anti-money laundering program and an obligation to report suspicious transactions under this chapter.

(j) *Definitions.* For purposes of this section, the following terms have the following meanings.

(1) *Beneficial owner*—(i) *Beneficial owners of transferee entities.* (A) The beneficial owners of a transferee entity are the individuals who would be the beneficial owners of the transferee entity on the date of closing if the transferee entity were a reporting

company under 31 CFR 1010.380(d) on the date of closing.

(B) The beneficial owners of a transferee entity that is established as a non-profit corporation or similar entity, regardless of jurisdiction of formation, are limited to individuals who exercise substantial control over the entity, as defined in 31 CFR 1010.380(d)(1) on the date of closing.

(ii) *Beneficial owners of transferee trusts.* The beneficial owners of a transferee trust are the individuals who fall into one or more of the following categories on the date of closing:

(A) A trustee of the transferee trust.

(B) An individual other than a trustee with the authority to dispose of transferee trust assets.

(C) A beneficiary who is the sole permissible recipient of income and principal from the transferee trust or who has the right to demand a distribution of, or withdraw, substantially all of the assets from the transferee trust.

(D) A grantor or settlor who has the right to revoke the transferee trust or otherwise withdraw the assets of the transferee trust.

(E) A beneficial owner of any legal entity that holds at least one of the positions in the transferee trust described in paragraphs (j)(1)(ii)(A) through (D) of this section, except when the legal entity meets the criteria set forth in paragraphs (j)(10)(ii)(A) through (P) of this section. Beneficial ownership of any such legal entity is determined under 31 CFR 1010.380(d), utilizing the criteria for beneficial owners of a reporting company.

(F) A beneficial owner of any trust that holds at least one of the positions in the transferee trust described in paragraphs (j)(1)(ii)(A) through (D) of this section, except when the trust meets the criteria set forth in paragraphs (j)(11)(ii)(A) through (D). Beneficial ownership of any such trust is determined under this paragraph (j)(1)(ii)(F), utilizing the criteria for beneficial owners of a transferee trust.

(2) *Closing or settlement agent.* The term “closing or settlement agent” means any person, whether or not acting as an agent for a title agent or company, a licensed attorney, real estate broker, or real estate salesperson, who for another and with or without a commission, fee, or other valuable consideration and with or without the intention or expectation of receiving a commission, fee, or other valuable consideration, directly or indirectly, provides closing or settlement services incident to the transfer of residential real property.

(3) *Closing or settlement statement.* The term “closing or settlement

statement” means the statement of receipts and disbursements for a transfer of residential real property.

(4) *Date of closing.* The term “date of closing” means the date on which the transferee entity or transferee trust receives an ownership interest in residential real property.

(5) *Ownership interest.* The term “ownership interest” means the rights held in residential real property that are demonstrated:

(i) Through a deed, for a reportable transfer described in paragraph (b)(1)(i) or (ii) of this section; or

(ii) Through stock, shares, membership, certificate, or other contractual agreement evidencing ownership, for a reportable transfer described in paragraph (b)(1)(iii) of this section.

(6) *Recordation office.* The term “recordation office” means any State, local, or Tribal office for the recording of reportable transfers as a matter of public record.

(7) *Residential real property.* The term “residential real property” means:

(i) Real property located in the United States containing a structure designed principally for occupancy by one to four families;

(ii) Vacant or unimproved land located in the United States zoned, or for which a permit has been issued, for the construction of a structure designed principally for occupancy by one to four families; or

(iii) Shares in a cooperative housing corporation.

(8) *Signing individual.* The term “signing individual” means each individual who signed documents on behalf of the transferee as part of the reportable transfer. However, it does not include any individual who signed documents as part of their employment with a financial institution that has both an obligation to maintain an anti-money laundering program and an obligation to report suspicious transactions under this chapter.

(9) *Statutory trust.* The term “statutory trust” means any trust created or authorized under the Uniform Statutory Trust Entity Act or as enacted by a State. For the purposes of this subpart, statutory trusts are transferee entities.

(10) *Transferee entity.* (i) Except as set forth in paragraph (j)(10)(ii) of this section, the term “transferee entity” means any person other than a transferee trust or an individual.

(ii) A transferee entity does not include:

(A) A securities reporting issuer defined in 31 CFR 1010.380(c)(2)(i);

(B) A governmental authority defined in 31 CFR 1010.380(c)(2)(ii);

(C) A bank defined in 31 CFR 1010.380(c)(2)(iii);

(D) A credit union defined in 31 CFR 1010.380(c)(2)(iv);

(E) A depository institution holding company defined in 31 CFR 1010.380(c)(2)(v);

(F) A money service business defined in 31 CFR 1010.380(c)(2)(vi);

(G) A broker or dealer in securities defined in 31 CFR 1010.380(c)(2)(vii);

(H) A securities exchange or clearing agency defined in 31 CFR 1010.380(c)(2)(viii);

(I) Any other Exchange Act registered entity defined in 31 CFR 1010.380(c)(2)(ix);

(J) An insurance company defined in 31 CFR 1010.380(c)(2)(xii);

(K) A State-licensed insurance producer defined in 31 CFR 1010.380(c)(2)(xiii);

(L) A Commodity Exchange Act registered entity defined in 31 CFR 1010.380(c)(2)(xiv);

(M) A public utility defined in 31 CFR 1010.380(c)(2)(xvi);

(N) A financial market utility defined in 31 CFR 1010.380(c)(2)(xvii);

(O) An investment company as defined in section 3(a) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(a)) that is registered with the Securities and Exchange Commission (SEC) under section 8 of the Investment Company Act (15 U.S.C. 80a–8); and

(P) Any legal entity whose ownership interests are controlled or wholly owned, directly or indirectly, by an entity described in paragraphs (j)(10)(ii)(A) through (O) of this section.

(11) *Transferee trust.* (i) Except as set forth in paragraph (j)(11)(ii) of this section, the term “transferee trust” means any legal arrangement created when a person (generally known as a settlor or grantor) places assets under the control of a trustee for the benefit of one or more persons (each generally known as a beneficiary) or for a specified purpose, as well as any legal arrangement similar in structure or function to the above, whether formed under the laws of the United States or a foreign jurisdiction. A trust is deemed to be a transferee trust regardless of whether residential real property is titled in the name of the trust itself or in the name of the trustee in the trustee’s capacity as the trustee of the trust.

(ii) A transferee trust does not include:

(A) A trust that is a securities reporting issuer defined in 31 CFR 1010.380(c)(2)(i);

(B) A trust in which the trustee is a securities reporting issuer defined in 31 CFR 1010.380(c)(2)(i);

(C) A statutory trust; or

(D) An entity wholly owned by a trust described in paragraphs (j)(11)(ii)(A) through (C) of this section.

(k) *Filing procedures*—(1) *What to file*. A reportable transfer shall be reported by completing a Real Estate Report and collecting and maintaining supporting documentation as required by this section.

(2) *Where to file*. The Real Estate Report shall be filed electronically with FinCEN, as indicated in the instructions to the report.

(3) *When to file*. A reporting person is required to file a Real Estate Report no later than 30 calendar days after the date of closing.

(l) *Retention of records*. A reporting person shall maintain a copy of any Real Estate Report filed by the reporting person and a copy of any certification described in paragraph (e)(3) of this section. In addition, all parties to a designation agreement described in paragraph (c)(3) of this section shall maintain a copy of such designation agreement.

(m) *Exemptions*—(1) *Confidentiality*. Reporting persons, and any director, officer, employee, or agent of such persons, and Federal, State, local, or Tribal government authorities, are exempt from the confidentiality provision in 31 U.S.C. 5318(g)(2) that prohibits the disclosure to any person involved in a suspicious transaction that the transaction has been reported or any

information that otherwise would reveal that the transaction has been reported.

(2) *Anti-money laundering program*. A reporting person under this section is exempt from the requirement to establish an anti-money laundering program, in accordance with 31 CFR 1010.205(b)(1)(v). However, as provided in 31 CFR 1010.205(c), no such exemption applies for a financial institution that is otherwise required to establish an anti-money laundering program by this chapter.

§ 1031.321 [Reserved]

Andrea M. Gacki,

Director, Financial Crimes Enforcement Network.

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Part III

Department of Health and Human Services

42 CFR Part 2

Confidentiality of Substance Use Disorder (SUD) Patient Records; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2

RIN 0945-AA16

Confidentiality of Substance Use Disorder (SUD) Patient Records

AGENCY: Office for Civil Rights, Office of the Secretary, Department of Health and Human Services; Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The United States Department of Health and Human Services (HHS or “Department”) is issuing this final rule to modify its regulations to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The Department is issuing this final rule after careful consideration of all public comments received in response to the notice of proposed rulemaking

(NPRM) for the Confidentiality of Substance Use Disorder (SUD) Patient Records. This final rule also makes certain other modifications to increase alignment with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to improve workability and decrease burden on programs, covered entities, and business associates.

DATES:

Effective date: This final rule is effective on April 16, 2024.

Compliance date: Persons subject to this regulation must comply with the applicable requirements of this final rule by February 16, 2026.

FOR FURTHER INFORMATION CONTACT:

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TABLE OF ACRONYMS

Acronym	Meaning
ACO	Accountable Care Organization.
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act.
ADT	Admit, Discharge, Transfer.
APCD	All-Payer Claims Database.
BLS	Bureau of Labor Statistics.
CARES Act	Coronavirus Aid, Relief, and Economic Security Act.
CBO	Community-based Organizations.
CFR	Code of Federal Regulations.
CHIP	Children’s Health Insurance Program.
CMP	Civil Money Penalty.
CMS	Centers for Medicare & Medicaid Services.
COVID–19	Coronavirus Disease 2019.
CSP	Cloud Service Provider.
DOJ	U.S. Department of Justice.
E.O.	Executive Order.
EHR	Electronic Health Record.
ePHI	Electronic Protected Health Information.
FDA	Food and Drug Administration.
FOIA	Freedom of Information Act.
FR	Federal Register.
GS	General Schedule.
Health IT	Health Information Technology.
HHS or Department	U.S. Department of Health and Human Services.
HIE	Health Information Exchange.
HIN	Health Information Network.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009.
HIV	Human Immunodeficiency Virus.
ICR	Information Collection Request.
IHS	Indian Health Service.
ISDEAA	Indian Self-Determination and Education Assistance Act.
MAT	Medication Assisted Treatment.
MHPAEA	Mental Health Parity and Addiction Equity Act.
MOUD	Medications for Opioid Use Disorder.
MPCD	Multi-Payer Claims Database.
NIST	National Institute of Standards and Technology.
NOAA	National Oceanic and Atmospheric Administration.
NPP	Notice of Privacy Practices.
NPRM	Notice of Proposed Rulemaking.

TABLE OF ACRONYMS—Continued

Acronym	Meaning
N-SSATS	National Survey of Substance Abuse Treatment Services.
OCR	Office for Civil Rights.
OIG	Office of the Inspector General.
OIRA	Office of Information and Regulatory Affairs.
OMB	Office of Management and Budget.
ONC	Office of the National Coordinator for Health Information Technology.
OTP	Opioid Treatment Program.
PDMP	Prescription Drug Monitoring Program.
PHI	Protected Health Information.
PHSA	Public Health Service Act.
PRA	Paperwork Reduction Act of 1995.
Pub. L.	Public Law.
QSO	Qualified Service Organization.
QSOA	Qualified Service Organization Agreement.
RFA	Regulatory Flexibility Act.
RFI	Request for Information.
RIA	Regulatory Impact Analysis.
RPMS	Resource and Patient Management System.
SAMHSA	Substance Abuse and Mental Health Services Administration.
SBA	Small Business Administration.
SUD	Substance Use Disorder.
TEDS	Treatment Episode Data Set.
TEFCA	Trusted Exchange Framework and Common Agreement.
TPO	Treatment, Payment, and/or Health Care Operations.
U.S.C.	United States Code.
USPHS	U.S. Public Health Service.
VA	U.S. Department of Veterans Affairs.

I. Executive Summary

A. Purpose of Rulemaking and Issuance of Proposed Rule

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security (CARES) Act, including section 3221 of the Act¹ entitled “Confidentiality and Disclosure of Records Relating to Substance Use Disorder.” Section 3221 enacts statutory amendments to section 290dd–2 of title 42 United States Code (42 U.S.C. 290dd–2).² These amendments require the U.S. Department of Health and Human Services (HHS or “Department”) to increase the regulatory alignment between title 42 of the Code of Federal Regulations (CFR) (42 CFR part 2 or “part 2”),³ which includes privacy provisions that protect SUD patient records, and key aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁴

Privacy, Breach Notification, and Enforcement regulations (“HIPAA regulations”),⁵ which govern the use and disclosure of protected health information (PHI).⁶

On December 2, 2022, the Department published a notice of proposed rulemaking (NPRM) proposing to modify part 2 consistent with the requirements of section 3221.⁷ In the NPRM, the Department proposed to: (1) enhance restrictions against the use and

Health (HITECH) Act of 2009, Public Law 111–5, 123 Stat. 226 (Feb. 17, 2009) (codified at 42 U.S.C. 139w–4(0)(2)), enacted as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5, 123 Stat. 226 (Feb. 17, 2009).

⁵ See the HIPAA Privacy Rule, 45 CFR parts 160 and 164, subparts A and E; the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C; the HIPAA Breach Notification Rule, 45 CFR part 164, subpart D; and the HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E. Breach notification requirements were added by the HITECH Act.

⁶ PHI is individually identifiable health information maintained or transmitted by or on behalf of a HIPAA covered entity. See 45 CFR 160.103 (definitions of “Individually identifiable health information” and “Protected health information”).

⁷ 87 FR 74216 (Dec. 2, 2022). The Department also proposed modifications to the HIPAA Notice of Privacy Practices (NPP) in January 2021 and April 2023. See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446 (Jan. 21, 2021) and HIPAA Privacy Rule To Support Reproductive Health Care Privacy 88 FR 23506 (Apr. 17, 2023).

disclosure of part 2 records⁸ in civil, criminal, administrative, and legislative proceedings; (2) provide for civil enforcement authority, including the imposition of civil money penalties (CMPs); (3) modify consent for uses and disclosures of part 2 records for treatment, payment, and health care operations (TPO) purposes; (4) impose breach notification obligations; (5) incorporate some definitions from the HIPAA regulations into part 2; (6) provide new patient rights to request restrictions on uses and disclosures and obtain an accounting of disclosures made with consent; (7) add a permission to disclose de-identified records to public health authorities; and (8) address concerns about potential unintended consequences for government agencies that investigate part 2 programs due to the change in enforcement authority and penalties for violations of part 2.

The 60-day public comment period for the proposed rule closed on January 31, 2023, and the Department received approximately 220 comments in response to its proposal.⁹ After considering the public comments, the Department is issuing this final rule that adopts many of the proposals set forth

⁸ Within this rule the terms records and part 2 records are used interchangeably to refer to information subject to part 2.

⁹ The public comments are available at <https://www.regulations.gov/docket/HHS-OCR-2022-0018/comments>.

¹ Public Law 116–136, 134 Stat. 281 (Mar. 27, 2020).

² 42 U.S.C. 290dd–2.

³ For readability, the Department refers to specific sections of 42 CFR part 2 using a shortened citation with the “§” symbol except where necessary to distinguish title 42 citations from other CFR titles, such as title 45 CFR, and in footnotes where the full reference is used.

⁴ Subtitle F of title II of HIPAA, Public Law 104–191, 110 Stat. 1936 (Aug. 21, 1996) added a new part C to title XI of the Social Security Act (SSA), Public Law 74–271, 49 Stat. 620 (Aug. 14, 1935), (see sections 1171–1179 of the SSA (codified at 42 U.S.C. 1320d–1320d–8)), as amended by the Health Information Technology for Economic and Clinical

in the NPRM, with certain modifications based on the input received. This final rule aligns certain part 2 requirements more closely with requirements of the HIPAA regulations to improve the ability of entities that are subject to part 2 to use and disclose part 2 records and make other changes to part 2, as described in this preamble. We believe this final rule implements the modifications required by the CARES Act amendments to 42 U.S.C. 290dd–2 and will decrease burdens on patients and providers, improve coordination of care and access to care and treatment, and protect the confidentiality of treatment records.

The provisions of the proposed rule and the public comments received that were within the scope of the proposed rule are described in more detail below in sections III and IV.

B. Severability

In this final rule, we adopt modifications to 42 CFR part 2 that support a unified scheme of privacy protections for part 2 records. While the unity and comprehensiveness of this scheme maximizes its utility, we clarify that its constituent elements operate independently to protect patient privacy. Were a provision of this regulation stayed or invalidated by a reviewing court, the provisions that remain in effect would continue to provide vital patient privacy protections. For example, the essential part 2 provisions concerning such issues as restrictions on use of part 2 records in criminal, civil, and administrative proceedings and written consent requirements would remain in effect even if certain other provisions, such as the limitation on civil or criminal liability in § 2.3(b), were no longer in effect. Similarly, the provisions regulating different forms of conduct under part 2 (*e.g.*, use, disclosure, consent requirements) each provide distinct benefits for patient privacy. Thus, we consider the provisions adopted in this final rule to be severable, both internally within this final rule and from the other provisions in part 2, and the Department's intent is to preserve the rule in its entirety, and each independent provision of the rule, to the fullest extent possible.

Accordingly, any provision of 42 CFR part 2 that is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, should be construed so as to give maximum effect to the provision permitted by law, unless such holding is one of utter invalidity or unenforceability, in which event the provision is intended to be severable from this part and not affect

the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

C. Summary of the Major Provisions

After consideration of the public comments received in response to the NPRM, the Department is issuing this final rule as follows:¹⁰

1. Section 2.1—Statutory Authority for Confidentiality of Substance Use Disorder Patient Records

Finalizes § 2.1 to more closely reflect the authority granted in 42 U.S.C. 290dd–2(g), including with respect to court orders authorizing the disclosure of records under 42 U.S.C. 290dd–2(b)(2)(C).

2. Section 2.2—Purpose and Effect

Finalizes paragraph (b) of § 2.2 to compel disclosures to the Secretary¹¹ that are necessary for enforcement of this rule, using language adapted from the HIPAA Privacy Rule at 45 CFR 164.502(a)(2)(ii). Finalizes a new paragraph (b)(3) that prohibits any limits on a patient's right to request restrictions on use of records for TPO or a covered entity's¹² choice to obtain consent to use or disclose records for TPO purposes as provided in the HIPAA Privacy Rule. References “use and disclosure” in § 2.2(a) and (b). Removes reference to criminal penalty and finalizes new paragraph (b)(3).

3. Section 2.3—Civil and Criminal Penalties for Violations

Finalizes the heading of this section as above. This section as finalized now references the HIPAA enforcement authorities in the Social Security Act at sections 1176 (civil enforcement, including the culpability tiers established by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009) and 1177

¹⁰ Additional revisions are not listed here because they are not considered major. Generally, the proposals not listed make non-substantive changes. These proposals are reviewable in section IV and the amendatory language in the last section of the final rule and include proposals to modify § 2.17 (Undercover agents and informants); § 2.20 (Relationship to state laws); § 2.21 (Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity); and § 2.34 (Uses and Disclosures to prevent multiple enrollments).

¹¹ Unless otherwise stated, “Secretary” as used in this rule refers to the Secretary of HHS.

¹² Covered entities are health care providers who transmit health information electronically in connection with any transaction for which the Department has adopted an electronic transaction standard, health plans, and health care clearinghouses. See 45 CFR 160.103 (definition of “Covered entity”).

(criminal penalties),¹³ as implemented in the HIPAA Enforcement Rule.¹⁴ Paragraph (b) includes a limitation on civil or criminal liability (“safe harbor”) under part 2 for investigative agencies that act with reasonable diligence before making a demand for records in the course of an investigation or prosecution of a part 2 program or person holding the record, provided that certain conditions are met.¹⁵ Further modifies the “reasonable diligence” steps to mean taking all of the following actions: searching for the practice or provider among the SUD treatment facilities in SAMHSA's online treatment locator; searching in a similar state database of treatment facilities where available; checking a practice or program's website, where available, or physical location; viewing the entity's Patient Notice or HIPAA NPP if it is available; and taking all these steps within no more than 60 days before requesting records or placing an undercover agent or informant. Updates language referring to enforcement, now set forth in paragraph (c).

4. Section 2.4—Complaints of Noncompliance

Modifies the heading to refer to “Complaints of noncompliance.” Finalizes inclusion of requirements consistent with those applicable to HIPAA complaints under 45 CFR 164.530(d), (g), and (h), including: a requirement for a part 2 program to establish a process to receive complaints. Adds a new provision permitting patients to file complaints with the Secretary in the same manner as under 45 CFR 160.306. Finalizes a prohibition against taking adverse action against patients who file complaints and a prohibition against requiring patients to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.

5. Section 2.11—Definitions

Finalizes definitions of the following terms within this part consistent with the NPRM: “Breach,” “Business associate,” “Covered entity,” “Health

¹³ See Public Law 111–5, 123 Stat. 226 (Feb. 17, 2009). Section 13410 of the HITECH Act (codified at 42 U.S.C. 17939) amended sections 1176 and 1177 of the Social Security Act (codified at 42 U.S.C. 1320d–5 and 1320d–6) to add civil and criminal penalty tiers for violations of the HIPAA Administrative Simplification provisions.

¹⁴ See 45 CFR part 160 subparts C, D, and E.

¹⁵ Although this provision is not expressly required by the CARES Act, it falls within the Department's general rulemaking authority in 42 U.S.C. 290dd–2(g), and is needed to address the logical consequences of the changes required by sec. 3221.

care operations,” “HIPAA,” “HIPAA regulations,” “Informant,” “Part 2 program director,” “Program,” “Payment,” “Person,” “Public health authority,” “Records,” “Substance use disorder (SUD),” “Third-party payer,” “Treating provider relationship,” “Treatment,” “Unsecured protected health information,” “Unsecured record,” and “Use.” Adds a definition of “Substance Use Disorder (SUD) counseling notes” on which input was requested in the NPRM. Adds new definitions of “Lawful holder” and “Personal representative.” Adopts a revised definition of “Intermediary,” but with an exclusion for part 2 programs, covered entities, and business associates. Modifies definition of “Investigative agency” to reference state, local, territorial, and Tribal investigative agencies. Modifies definition of “Patient identifying information” to ensure consistency with the de-identification standard incorporated into this final rule. Modifies the proposed definition of “Qualified Service Organization” (QSO) to expressly include business associates as QSOs where the QSO meets the definition of business associate for a covered entity that is also a part 2 program.

6. Section 2.12—Applicability

Replaces “Armed Forces” with “Uniformed Services” in paragraphs (b)(1) and (c)(2) of § 2.12. Incorporates four statutory examples of restrictions on the use or disclosure of part 2 records to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient. Adds language to qualify the term “Third-party payer” with the phrase “as defined in this part.” Specifies that a part 2 program, covered entity, or business associate¹⁶ that receives records based on a single consent for all future uses and disclosures for TPO is not required to segregate or segment such records. Revises paragraph (e)(4)(i) to clarify when a diagnosis is not covered by part 2.

7. Section 2.13—Confidentiality Restrictions and Safeguards

Finalizes the redesignation of § 2.13(d) requiring a list of disclosures as new § 2.24 and modifies the text for clarity.

¹⁶ A business associate is a person, other than a workforce member, that performs certain functions or activities for or on behalf of a covered entity, or that provides certain services to a covered entity involving the disclosure of PHI to the person. *See* 45 CFR 160.103 (definition of “Business associate”).

8. Section 2.14—Minor Patients

Finalizes the change of the verb “judges” to “determines” to describe a part 2 program director’s evaluation and decision that a minor lacks decision making capacity.

9. Section 2.15—Patients Who Lack Capacity and Deceased Patients

Finalizes changes proposed in the NPRM. Changes the heading as above. Replaces outdated terminology and clarifies that paragraph (a) of this section refers to an adjudication by a court of a patient’s lack of capacity to make health care decisions while paragraph (b) refers to a patient’s lack of capacity to make health care decisions without court adjudication. Clarifies consent for uses and disclosures of records by personal representatives for patients who lack capacity to make health care decisions in paragraph (a) and deceased patients in paragraph (b)(2).

10. Section 2.16—Security for Records and Notification of Breaches

Finalizes changes proposed in the NPRM. Changes the heading as above. Finalizes the de-identification provision to align with the HIPAA Privacy Rule standard at 45 CFR 164.514. Creates an exception to the requirement that part 2 programs and lawful holders create policies and procedures to secure records that applies to family, friends, and other informal caregivers who are lawful holders as defined in this regulation. Applies the HITECH Act breach notification provisions¹⁷ that are currently implemented in the HIPAA Breach Notification Rule to breaches of records by part 2 programs. Modifies the exemption for lawful holders by exempting them from § 2.16(a) instead of only paragraph (a)(1).

11. Section 2.19—Disposition of Records by Discontinued Programs

Finalizes an exception to clarify that these provisions do not apply to transfers, retrocessions, and reassumptions of part 2 programs pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), to facilitate the responsibilities set forth in 25 U.S.C. 5321(a)(1), 25 U.S.C. 5384(a), 25 U.S.C. 5324(e), 25 U.S.C. 5330, 25 U.S.C. 5386(f), 25 U.S.C. 5384(d), and the implementing ISDEAA regulations. Updates the language to refer to “non-

¹⁷ Section 13400 of the HITECH Act (codified at 42 U.S.C. 17921) defined the term “Breach”. Section 13402 of the HITECH Act (codified at 42 U.S.C. 17932) enacted breach notification provisions, discussed in detail below.

electronic” records and include “paper” records as an example of non-electronic records.

12. Section 2.22—Notice to Patients of Federal Confidentiality Requirements

Finalizes proposed changes to requirements for notice to patients of Federal confidentiality requirements (hereinafter, “Patient Notice”) to address protections required by 42 U.S.C. 290dd–2, as amended by section 3221 of the CARES Act. Modifies the statement of a patient’s right to discuss the notice with a designated contact person by permitting the part 2 program to list an office rather than naming a person. Further modifies the list of patient rights to include the following: (1) a right to a list of disclosures by an intermediary for the past 3 years as provided in § 2.24 (moved from the consent requirements in § 2.31); and (2) a right to elect not to receive any fundraising communications to fundraise for the benefit of the part 2 program. Further modifies the fundraising provision by replacing the proposed requirement to obtain patient consent with a requirement to provide individuals with the opportunity to opt out of receiving fundraising communications, which more closely aligns with the HIPAA regulations. Clarifies that a court order authorizing use or disclosure must be accompanied by a subpoena or similar legal mandate compelling disclosure.

13. Section 2.23—Patient Access and Restrictions on Use and Disclosure

Finalizes the heading as above. Adds the term “disclosure” to the heading and body of this section to clarify that information obtained by patient access to their record may not be used or disclosed for purposes of a criminal charge or criminal investigation.

14. Section 2.24—Requirements for Intermediaries

Finalizes the retitling of the redesignated section that is moved from § 2.13(d) as above to clarify the responsibilities of recipients of records received under a consent with a general designation (other than part 2 programs, covered entities, and business associates), such as research institutions, accountable care organizations (ACOs), and care management organizations.

15. Section 2.25—Accounting of Disclosures

Finalizes this new section to implement 42 U.S.C. 290dd–2(b)(1)(B), as amended by the section 3221 of the CARES Act, to add a right to an

accounting of all disclosures made with consent for up to three years prior to the date the accounting is requested. A separate provision applies to disclosures for TPO purposes made through an EHR. The compliance date for § 2.25 is tolled until the HIPAA Accounting of Disclosures provision at 45 CFR 164.528 is revised to address accounting for TPO disclosures made through an EHR.

16. Section 2.26—Right To Request Privacy Protection for Records

Finalizes this new section to implement 42 U.S.C. 290dd–2(b)(1)(B), as amended by the section 3221 of the CARES Act, to incorporate into part 2 the rights set forth in the HIPAA Privacy Rule at 45 CFR 164.522, including: (1) a patient right to request restrictions on disclosures of records otherwise permitted for TPO purposes, and (2) a patient right to obtain restrictions on disclosures to health plans for services paid in full by the patient.

17. Subpart C—Uses and Disclosures With Patient Consent

Finalizes change to the heading of subpart C as above to reflect changes made to the provisions of this subpart related to the consent to use and disclose part 2 records, consistent with 42 U.S.C. 290dd–2(b), as amended by the section 3221(b) of the CARES Act.

18. Section 2.31—Consent Requirements

Finalizes the proposed alignment of the content requirements for part 2 written consent with the content requirements for a valid HIPAA authorization and clarifies how recipients may be designated in a consent to use and disclose part 2 records for TPO. Further modifies the rule by replacing the proposed requirement to obtain consent for fundraising with an opportunity for the patient to opt out. Adds consent provisions for uses and disclosures of SUD counseling notes, and adds an express requirement for separate consent for use and disclosure of records in civil, criminal, administrative, or legislative proceedings.

19. Section 2.32—Notice and Copy of Consent To Accompany Disclosure

Further modifies the proposed heading to read as above by inserting “and copy of consent”. Finalizes the proposed alignment of the content requirements for the required notice that accompanies a disclosure of records (hereinafter “Notice to Accompany Disclosure”) with the requirements of 42 U.S.C. 290dd–2(b), as amended by section 3221(b) of the CARES Act.

Further modifies this section by creating a new requirement that each disclosure made with the patient’s written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided.

20. Section 2.33—Uses and Disclosures Permitted With Written Consent

Changes the heading as proposed, to read as above. Aligns this provision with the statutory authority in 42 U.S.C. 290dd–2(b)(1), as amended by section 3221(b) of the CARES Act. Replaces the provisions requiring consent for uses and disclosures for payment and certain health care operations with permission to use and disclose records for TPO with a single consent given once for all such future uses and disclosures (“TPO consent”) as permitted by the HIPAA regulations, until such time as the patient revokes the consent in writing. Finalizes proposed redisclosure permissions for three categories of recipients of part 2 records pursuant to a written consent with some additional modifications to limit the ability to redisclose part 2 records in accordance with HIPAA to covered entities and business associates, as follows: (1) permits a covered entity or business associate that receives part 2 records pursuant to a TPO consent to redisclose the records in accordance with the HIPAA regulations, except for certain proceedings against the patient;¹⁸ (2) permits a part 2 program that is not a covered entity to redisclose records received pursuant to a TPO consent according to the consent; and (3) permits a lawful holder that is not a covered entity or business associate to redisclose part 2 records for payment and health care operations to its contractors, subcontractors, or legal representatives as needed to carry out the activities specified in the consent. Finalizes the contracting requirements in paragraph (c) to exclude covered entities and business associates because they are subject to HIPAA business associate agreement requirements.

21. Section 2.35—Disclosures to Elements of the Criminal Justice System Which Have Referred Patients

Finalizes the proposals to replace “individuals” with “persons” and clarifies that permitted redisclosures of information are from part 2 records.

22. Subpart D—Uses and Disclosures Without Patient Consent

Finalizes the proposal to change the heading of subpart D to reflect changes made to the provisions of this subpart

related to the consent to use and disclose part 2 records, consistent with 42 U.S.C. 290dd–2 as amended by the CARES Act.

23. Section 2.51—Medical Emergencies

Finalizes the proposal to replace the term “individual” with the term “person” in § 2.51(c)(2).

24. Section 2.52—Scientific Research

Finalizes the proposed modifications to the heading as above to reflect statutory language. The final rule further aligns with the HIPAA Privacy Rule by replacing the requirements to render part 2 data in research reports non-identifiable with the HIPAA Privacy Rule’s de-identification standard in 45 CFR 164.514.

25. Section 2.53—Management Audits, Financial Audits, and Program Evaluation

Finalizes changes as proposed. Modifies the heading to reflect statutory language. To support implementation of 42 U.S.C. 290dd–2(b)(1), as amended by section 3221(b) of the CARES Act, adds a provision to acknowledge the permission to use and disclose records for health care operations purposes based on written consent of the patient and the permission to redisclose such records as permitted by the HIPAA Privacy Rule if the recipient is a part 2 program, covered entity, or business associate.

26. Section 2.54—Disclosures for Public Health

Finalizes the proposed addition of this section to implement 42 U.S.C. 290dd–2(b)(2)(D), as amended by section 3221(c) of the CARES Act, to permit the disclosure of records without patient consent to public health authorities provided that the records disclosed are de-identified according to the standards established in section 45 CFR 164.514.

27. Subpart E—Court Orders Authorizing Use and Disclosure

Finalizes proposed modifications to the heading of subpart E as above to reflect changes made to the provisions of this subpart related to the uses and disclosure of part 2 records in proceedings consistent with 42 U.S.C. 290dd–2(b) and (2)(c), as amended by sections 3221(b) and (e) of the CARES Act.

28. Section 2.62—Order Not Applicable to Records Disclosed Without Consent to Researchers, Auditors, and Evaluators

Finalizes the proposed replacement of the term “qualified personnel” with a

¹⁸ See 42 U.S.C. 290dd–2(b)(1)(B) and (c).

reference to the criteria that define such persons and adds a reference to § 2.53 as a technical edit.

29. Section 2.63—Confidential Communications

Finalizes proposed changes to paragraph (a)(3) of § 2.63 to expressly include civil, criminal, administrative, and legislative proceedings as forums where the requirements for a court order under this part would apply, to implement 42 U.S.C. 290dd–2(c), as amended by section 3221(c) of the CARES Act.

30. Section 2.64—Procedures and Criteria for Orders Authorizing Uses and Disclosures for Noncriminal Purposes

Finalizes proposed changes that expand the types of forums where restrictions on use and disclosure of records in civil proceedings against patients apply¹⁹ to expressly include administrative and legislative proceedings and also restricts the use of testimony conveying information in a record in civil proceedings against patients, absent consent or a court order.

31. Section 2.65—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Criminally Investigate or Prosecute Patients

Finalizes changes as proposed. Modifies the heading as above. Expands the types of forums where restrictions on uses and disclosure of records in criminal proceedings against patients apply²⁰ to expressly include administrative and legislative proceedings and also restricts the use of testimony conveying information in a part 2 record in criminal proceedings against patients, absent consent or a court order.

32. Section 2.66—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Investigate or Prosecute a Part 2 Program or the Person Holding the Records

Finalizes changes as proposed and adds new changes. Modifies the heading as above. Finalizes requirements for investigative agencies to follow in the event that they discover in good faith that they received part 2 records during an investigation or prosecution of a part 2 program or the person holding the records, in order to seek a court order as required under § 2.66. Adds a further modification to provide that information from records obtained in violation of this part cannot be used in an

application for a court order to obtain such records.

33. Section 2.67—Orders Authorizing the Use of Undercover Agents and Informants To Investigate Employees or Agents of a Part 2 Program in Connection With a Criminal Matter

Finalizes proposed criteria for issuance of a court order in instances where an application is submitted after the placement of an undercover agent or informant has already occurred, requiring an investigative agency to satisfy the conditions at § 2.3(b). Adds a further modification to provide that information from records obtained in violation of this part cannot be used in an application for a court order to obtain such records.

34. Section 2.68—Report to the Secretary

Finalizes the proposed requirement for investigative agencies to file annual reports about the instances in which they applied for a court order after receipt of part 2 records or placement of an undercover agent or informant as provided in §§ 2.66(a)(3) and 2.67(c)(4).

35. General Changes To Use and Disclosure

Finalizes proposed changes to re-order “disclosure and use” to “use and disclosure” throughout the regulation consistent with their usage in the HIPAA Privacy Rule which generally regulates the “use and disclosure” of PHI and relies on the phrase as a term of art.²¹ Inserts “use” or “disclose” to reflect the scope of activity that is the subject of the regulatory provision.

D. Summary of the Costs and Benefits of the Major Provisions

This final rule is anticipated to have an annual effect on the economy of \$12,720,000 in the first year of the rule, followed by net savings in years two through five, resulting in overall net cost savings of \$8,445,706 over five years. The Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action under section 3(f) of E.O. 12866, but not under section 3(f)(1).

Accordingly, the Department has prepared a Regulatory Impact Analysis (RIA) that presents the estimated costs and benefits of the rule.

II. Statutory and Regulatory Background

Confidentiality of SUD Records

Congress enacted the first Federal confidentiality protections for SUD records in section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970.²² This statute authorized “persons engaged in research on, or treatment with respect to, alcohol abuse and alcoholism to protect the privacy of individuals who [were] the subject of such research or treatment” from persons not connected with the conduct of the research or treatment by withholding identifying information.

Section 408 of the Drug Abuse Office and Treatment Act of 1972²³ applied confidentiality requirements to records relating to drug abuse prevention authorized or assisted under any provision of the Act. Section 408 permitted disclosure, with a patient’s written consent, for diagnosis or treatment by medical personnel and to government personnel for obtaining patient benefits to which the patient is entitled. The 1972 Act also established exceptions to the consent requirement to permit disclosures for bona fide medical emergencies; to qualified personnel for conducting certain activities, such as scientific research or financial audit or program evaluation, as long as the patient is not identified in any reports; and as authorized by court order granted after application showing good cause.²⁴

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974²⁵ expanded the types of records protected by confidentiality restrictions to include records relating to “alcoholism,” “alcohol abuse”, and “drug abuse” maintained in connection with any program or activity conducted,

²² See sec. 333, Public Law 91–616, 84 Stat. 1853 (Dec. 31, 1970) (codified at 42 U.S.C. 2688h).

²³ See sec. 408, Public Law 92–255, 86 Stat. 65 (Mar. 21, 1972) (codified at 21 U.S.C. 1175). Section 408 also prohibited the use of a covered record for use or initiation or substantiation of criminal charges against a patient or investigation of a patient. Section 408 provided for a fine in the amount of \$500 for a first offense violation, and not more than \$5,000 for each subsequent offense.

²⁴ *Id.*

²⁵ See sec. 101, title I, Public Law 93–282, 88 Stat. 126 (May 14, 1974) (codified at 42 U.S.C. 4541 note), providing that: “This title [enacting this section and sections 4542, 4553, 4576, and 4577 of this title, amending sections 242a, 4571, 4572, 4573, 4581, and 4582 of this title, and enacting provisions set out as notes under sections 4581 and 4582 of this title] may be cited as the ‘Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974.’”

¹⁹ See 42 CFR part 2, subpart E.

²⁰ *Id.*

²¹ See, e.g., 45 CFR 164.502, Uses and disclosures of protected health information: General rules.

regulated, or directly or indirectly federally assisted by any United States agency. The 1974 Act also permitted the disclosure of records based on prior written patient consent only to the extent such disclosures were allowed under Federal regulations. Additionally, the 1974 Act excluded the interchange of records within the Armed Forces or components of the U.S. Department of Veterans Affairs (VA), then known as the Veterans' Administration, from the confidentiality restrictions.²⁶

In 1992, section 131 of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (ADAMHA Reorganization Act)²⁷ added section 543, Confidentiality of Records, to the Public Health Service Act (PHSA)²⁸ ("part 2 statute"), which narrowed the grounds upon which a court could grant an order permitting disclosure of such records from "good cause" (*i.e.*, based on weighing the public interest in the need for disclosure against the injury to the patient, physician patient relationship, and treatment services)²⁹ to "the need to avert a substantial risk of death or serious bodily harm."³⁰ Congress also established criminal penalties for part 2 violations under title 18 of the United States Code, Crimes and Criminal Procedure.³¹ Finally, section 543 granted broad authority to the Secretary of HHS to prescribe regulations to carry out the purposes of section 543 and provide for safeguards and procedures, including criteria for the issuance and scope of court orders to authorize disclosure of SUD records, "as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith."³²

In 1975, the Department promulgated the first Federal regulations implementing statutory SUD confidentiality provisions at 42 CFR part 2.³³ In 1987, the Department published a final rule making substantive changes to the scope of part 2 to clarify the regulations and ease the burden of compliance by part 2 programs within the parameters of the

existing statutory restrictions.³⁴ After the 1992 enactment of the ADAMHA Reorganization Act, the Department later clarified the definition of "program" in a 1995 final rule to narrow the scope of part 2 regulations pertaining to medical facilities to cover identified units within general medical facilities which holds themselves out as providing, and provide SUD treatment and medical personnel or other staff in a general medical care facility whose primary function is the provision of SUD diagnosis, treatment or referral for treatment and who are identified as such providers.³⁵

HIPAA and the HITECH Act

In 1996, Congress enacted HIPAA,³⁶ which included Administrative Simplification provisions requiring the establishment of national standards³⁷ to protect the privacy and security of individuals' PHI and establishing civil money and criminal penalties for violations of the requirements, among other provisions.³⁸ The Administrative Simplification provisions and implementing regulations apply to covered entities, which are health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.³⁹ Certain provisions of the HIPAA regulations also apply directly to "business associates" of covered entities.⁴⁰

³⁴ See 52 FR 21796 (June 9, 1987). See also Notice of Decision to Develop Regulations, 45 FR 53 (Jan. 2, 1980) and (Aug. 25, 1983).

³⁵ See 60 FR 22296 (May 5, 1995). See also 59 FR 42561 (Aug. 18, 1994) and 59 FR 45063 (Aug. 31, 1994). The ambiguity of the definition of "program" was identified in *United States v. Eide*, 875 F. 2d 1429 (9th Cir. 1989) where the court held that the general emergency room is a "program" as defined by the regulations.

³⁶ See Public Law 104–191, 110 Stat. 1936 (Aug. 21, 1996).

³⁷ See the Administrative Simplification provisions of title II, subtitle F, of HIPAA, *supra* note 4. See also sec. 264 of HIPAA (codified at 42 U.S.C. 1320d–2 note). See also, Centers for Medicare & Medicaid Services, "HIPAA and Administrative Simplification" (Sept. 6, 2023), <https://www.cms.gov/about-cms/what-we-do/administrative-simplification/hipaa/statutes-regulations>.

³⁸ See 42 U.S.C. 1320d–1–1320d–9. With respect to privacy standards, Congress directed the Department to "address at least the following: (1) The rights that an individual who is a subject of individually identifiable health information should have. (2) The procedures that should be established for the exercise of such rights. (3) The uses and disclosures of such information that should be authorized or required." 42 U.S.C. 1320d–2 note.

³⁹ See 42 U.S.C. 1320d–1 (applying Administrative Simplification provisions to covered entities).

⁴⁰ See "Office for Civil Rights Fact Sheet on Direct Liability of Business Associates under HIPAA" (May 2019) for a comprehensive list of requirements in the HIPAA regulations that apply directly to

The HIPAA Privacy Rule, including provisions implemented as a result of the HITECH Act,⁴¹ regulates the use and disclosure of PHI by covered entities and business associates, requires covered entities to have safeguards in place to protect the privacy of PHI, and requires covered entities to obtain the written authorization of an individual to use and disclose the individual's PHI unless the use or disclosure is otherwise required or permitted by the HIPAA Privacy Rule.⁴² The HIPAA Privacy Rule includes several use and disclosure permissions that are relevant to this NPRM, including the permissions for covered entities to use and disclose PHI without written authorization from an individual for TPO;⁴³ to public health authorities for public health purposes;⁴⁴ and for research in the form of a limited data set⁴⁵ or pursuant to a waiver of authorization by a Privacy Board or Institutional Review Board.⁴⁶ The HIPAA Privacy Rule also establishes the rights of individuals with respect to their PHI, including the rights to: receive adequate notice of a covered entity's privacy practices; request restrictions of certain uses and disclosures; access (*i.e.*, to inspect and obtain a copy of) their PHI; request an amendment of their PHI; and receive an accounting of certain disclosures of their PHI.⁴⁷ Finally, the HIPAA Privacy Rule specifies standards for de-identification of PHI such that, when implemented, the information is no longer individually identifiable health

business associates, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html>.

⁴¹ The HITECH Act extended the applicability of certain HIPAA Privacy Rule requirements and all of the HIPAA Security Rule requirements to the business associates of covered entities; required HIPAA covered entities and business associates to provide for notification of breaches of unsecured PHI (implemented by the HIPAA Breach Notification Rule); established new limitations on the use and disclosure of PHI for marketing and fundraising purposes; prohibited the sale of PHI; required consideration of whether a limited data set can serve as the minimum necessary amount of information for uses and disclosures of PHI; and expanded individuals' rights to access electronic copies of their PHI in an electronic health record (EHR), to receive an accounting of disclosures of their PHI with respect to electronic PHI (ePHI), and to request restrictions on certain disclosures of PHI to health plans. In addition, subtitle D strengthened and expanded HIPAA's enforcement provisions. See subtitle D of title XIII of the HITECH Act, entitled "Privacy", for all provisions (codified in title 42 of U.S.C.).

⁴² See 45 CFR 164.502(a).

⁴³ See 45 CFR 164.506.

⁴⁴ See 45 CFR 164.512(b).

⁴⁵ See 45 CFR 164.514(e)(1) through (4).

⁴⁶ See 45 CFR 164.512(i).

⁴⁷ See 45 CFR 164.520, 164.522, 164.524, 164.526 and 164.528.

²⁶ See sec. 408, title I, Public Law 92–255, 86 Stat. 79 (Mar. 21, 1972) (originally codified at 21 U.S.C. 1175). See 21 U.S.C. 1175 note for complete statutory history.

²⁷ See sec. 131, Public Law 102–321, 106 Stat. 323 (July 10, 1992) (codified at 42 U.S.C. 201 note).

²⁸ Codified at 42 U.S.C. 290dd–2.

²⁹ See sec. 333, Public Law 91–616, 84 Stat. 1853 (Dec. 31, 1970).

³⁰ See sec. 131, Public Law 102–321, 106 Stat. 323 (July 10, 1992) (codified at 42 U.S.C. 201 note).

³¹ *Id.*, adding sec. 543(b)(2)(C) to the PHSA.

³² *Id.*, adding sec. 543(g) to the PHSA.

³³ See 40 FR 27802 (July 1, 1975).

information subject to the HIPAA regulations.⁴⁸

The HIPAA Security Rule, codified at 45 CFR parts 160 and 164, subparts A and C, requires covered entities and their business associates to implement administrative, physical, and technical safeguards to protect electronic PHI (ePHI). Specifically, covered entities and business associates must ensure the confidentiality, integrity, and availability of all ePHI they create, receive, maintain, or transmit;⁴⁹ protect against reasonably anticipated threats or hazards to the security or integrity of the information⁵⁰ and reasonably anticipated impermissible uses or disclosures;⁵¹ and ensure compliance by their workforce.⁵²

The HIPAA Breach Notification Rule, codified at 45 CFR parts 160 and 164, subparts A and D, implements HITECH Act requirements⁵³ for covered entities to provide notification to affected individuals, the Secretary, and in some cases the media, following a “breach” of unsecured PHI. The HIPAA Breach Notification Rule also requires a covered entity’s business associate that experiences a breach of unsecured PHI to notify the covered entity of the breach. A breach is the acquisition, access, use, or disclosure of PHI in a manner not permitted by the HIPAA Privacy Rule that compromises the security or privacy of “unsecured” PHI, subject to three exceptions:⁵⁴ (1) the unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of a covered entity or business associate, if such acquisition, access, or use was made in good faith and within the scope of authority; (2) the inadvertent disclosure of PHI by a person authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the covered entity or business associate, or organized health care arrangement in which the covered entity participates; and (3) the covered entity or business associate making the disclosure has a good faith belief that the unauthorized person to whom the impermissible disclosure was made, would not reasonably have been able to retain the information.

The HIPAA Breach Notification Rule provides that a covered entity may rebut the presumption that such impermissible use or disclosure

constituted a breach by demonstrating that there is a low probability that PHI has been compromised based on a risk assessment of at least four required factors: (1) the nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification; (2) the unauthorized person who used the PHI or to whom the disclosure was made; (3) whether the PHI was actually acquired or viewed; and (4) the extent to which the risk to the PHI has been mitigated.⁵⁵

The HIPAA Enforcement Rule, codified at 45 CFR part 160 subparts C, D, and E, includes standards and procedures relating to investigations into complaints about noncompliance with the HIPAA regulation, compliance reviews, the imposition of CMPs, and procedures for hearings. The HIPAA Enforcement Rule states generally that the Secretary will impose a CMP upon a covered entity or business associate if the Secretary determines that the covered entity or business associate violated a HIPAA Administrative Simplification provision.⁵⁶ However, the HIPAA Enforcement Rule also provides for informal resolution of potential noncompliance,⁵⁷ which occurs through voluntary compliance by the regulated entity, corrective action, or a resolution agreement with the payment of a settlement amount to HHS Office for Civil Rights (OCR).

The Department promulgated or modified key provisions of the HIPAA regulations as part of the “Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act, and Other Modifications to the HIPAA Rules” final rule (“2013 Omnibus Final Rule”),⁵⁸ in which the Department implemented applicable provisions of the HITECH Act, among other modifications. For example, the Department strengthened privacy and security protections for PHI, finalized breach notification requirements, and enhanced enforcement by increasing potential CMPs for violations, including establishing tiers of penalties based on a covered entity’s or business associate’s level of culpability.⁵⁹

The Secretary of HHS delegated authority to OCR to make decisions

regarding the implementation and interpretation of the HIPAA Privacy, Security, Breach Notification, and Enforcement regulations.⁶⁰

Earlier Efforts To Align Part 2 With the HIPAA Regulations

Prior to amendment by the CARES Act, 42 U.S.C. 290dd–2 provided that records could be disclosed only with the patient’s prior written consent, with limited exceptions.⁶¹ The exceptions related to records maintained by VA or the Armed Forces and, for example, disclosures for continuity of care in emergency situations or between personnel who have a need for the information in connection with their duties that arise out of the provision of the diagnosis, treatment, or referral for treatment of patients with SUD.⁶² The exceptions did not include, for example, a disclosure of part 2 records by a part 2 program to a third-party medical provider to treat a condition other than SUD absent an emergency situation. Therefore, the current part 2 regulations require prior written consent of the patient for most uses and disclosures of part 2 records, including for non-emergency treatment purposes. In contrast, the HIPAA Privacy Rule permits covered entities to use and disclose an individual’s PHI for TPO without the individual’s HIPAA authorization.⁶³

The Department has modified and clarified part 2 several times to align certain provisions more closely with the HIPAA Privacy Rule,⁶⁴ address changes in health information technology (health IT), and provide greater flexibility for disclosures of patient identifying information within the health care system, while continuing to protect the confidentiality of part 2 records.⁶⁵ For example, the Department clarified in a 2017 final rule that the definition of “patient identifying information” in

⁶⁰ See U.S. Dep’t of Health and Human Servs., Office of the Secretary, Office for Civil Rights; Statement of Delegation of Authority, 65 FR 82381 (Dec. 28, 2000); U.S. Dep’t of Health and Human Servs., Office of the Secretary, Office for Civil Rights; Delegation of Authority, 74 FR 38630 (Aug. 4, 2009); U.S. Dep’t of Health and Human Servs., Office of the Secretary, Statement of Organization, Functions and Delegations of Authority, 81 FR 95622 (Dec. 28, 2016).

⁶¹ The limited exceptions are codified in current regulation at 42 CFR 2.12(c) and 42 CFR part 2, subpart D.

⁶² See 42 CFR 2.12(c)(3). These disclosures are limited to communications within a part 2 program or between a part 2 program and an entity having direct administrative control over the part 2 program.

⁶³ See 45 CFR 164.501.

⁶⁴ See 85 FR 42986 (July 15, 2020) and 83 FR 239 (Jan. 3, 2018).

⁶⁵ 82 FR 6052 (Jan. 18, 2017). See also 81 FR 6988 (Feb. 9, 2016).

⁴⁸ See 45 CFR 164.514(a) through (c).

⁴⁹ See 45 CFR 164.306(a)(1).

⁵⁰ See 45 CFR 164.306(a)(2).

⁵¹ See 45 CFR 164.306(a)(3).

⁵² See 45 CFR 164.306(a)(4).

⁵³ See sec. 13402 of the HITECH Act (codified at 42 U.S.C. 17932).

⁵⁴ See 45 CFR 164.402, “breach”, paragraph (1).

⁵⁵ *Id.* paragraph (2).

⁵⁶ Criminal penalties may be imposed by the Department of Justice for certain violations under 42 U.S.C. 1320d–6.

⁵⁷ See 45 CFR 160.304. See also 45 CFR 160.416 and 160.514.

⁵⁸ 78 FR 5566 (Jan. 25, 2013).

⁵⁹ *Id.*

part 2 includes the individual identifiers listed in the HIPAA Privacy Rule at 45 CFR 164.514(b)(2)(i) for those identifiers that are not already listed in the part 2 definition.⁶⁶ The 2017 final rule also revised § 2.16 (Security for Records) to more closely align with HIPAA and permitted the use of a consent that generally designates the recipient of records rather than naming a specific person.⁶⁷

In 2018, the Department issued a final rule clarifying the circumstances under which lawful holders and their legal representatives, contractors, and subcontractors could use and disclose part 2 records related to payment and health care operations in § 2.33(b) and for audit or evaluation-related purposes. The Department clarified that previously listed types of payment and health care operations uses and disclosures under the lawful holder permission in § 2.33(b) were illustrative, and not definitive so as to be included in regulatory text.⁶⁸ The Department also acknowledged the similarity of the list of activities to those included in the HIPAA Privacy Rule definition of “health care operations” but declined to fully incorporate that definition into part 2.⁶⁹ The Department specifically excluded care coordination and case management from the list of payment and health care operations activities permitted without prior written consent of the patient under part 2 based on a determination that these activities are akin to treatment.

In 2018 the Department also codified language for an abbreviated Notice to Accompany Disclosure of part 2 records.⁷⁰ Although the rule retained the requirement that a patient must consent before a lawful holder may redisclose part 2 records for treatment,⁷¹ the Department explained that the purpose of the part 2 regulations is to ensure that a patient receiving treatment for an SUD is not made more vulnerable by reason of the availability of their patient records than an individual with a SUD who does not seek treatment.⁷² The Department simultaneously recognized the legitimate needs of lawful holders to obtain payment and conduct health care operations as long as the core protections of part 2 are maintained.⁷³

In a final rule published July 15, 2020,⁷⁴ the Department retained the requirement that programs obtain prior written consent before disclosing part 2 records in the first instance (outside of recognized exceptions). At the same time the Department reversed its previous exclusion of care coordination and case management from the list of payment and health care operations in § 2.33(b) for which a lawful holder may make further disclosures to its contractors, subcontractors, and legal representatives.⁷⁵ The Department based this change on comments received on the proposed rule in 2019 and on section 3221(d)(4) of the CARES Act, which incorporated the HIPAA Privacy Rule definition of “health care operations,” including care coordination and case management activities,⁷⁶ into paragraph (k)(4) of 42 U.S.C. 290dd–2.⁷⁷ The July 2020 final rule also modified the consent requirements in § 2.31 by establishing special requirements for written consent⁷⁸ when the recipient of part 2 records is a health information exchange (HIE) (as defined in 45 CFR 171.102⁷⁹). In this final rule, the Department now finalizes a definition of the term “intermediary”⁸⁰ to further facilitate the exchange of part 2 records in new models of care, including those involving a research institution providing treatment, an ACO, or a care coordination or care management organization.⁸¹

⁷⁴ 85 FR 42986. See also 84 FR 44568 (Aug. 26, 2019).

⁷⁵ See 42 CFR 2.33(b).

⁷⁶ See 45 CFR 164.501.

⁷⁷ See 85 FR 42986, 43008–009. Sec. 3221(k)(4) expressed the Sense of Congress that the Department should exclude paragraph (6)(v) of 45 CFR 164.501 (relating to creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity) from the definition of “health care operations” in applying the definition to these records.

⁷⁸ See 85 FR 42986, 43006.

⁷⁹ *Id.* See also 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 FR 25642 (May 1, 2020).

⁸⁰ See 42 CFR 2.11, defining “Intermediary” as a person, other than a program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participants for the treatment of the patient(s)—e.g., a health information exchange, a research institution that is providing treatment, an accountable care organization, or a care management organization.

⁸¹ U.S. Dep’t of Health and Human Servs., “Information Related to Mental and Behavioral Health, including Opioid Overdose” (Dec. 23, 2022), <https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html>; U.S. Dep’t of Health and Human Servs., “Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party

The Department again modified part 2 on December 14, 2020,⁸² by amending the confidential communications section of § 2.63(a)(2), which enumerated a basis for a court order authorizing the use of a record when “the disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient.” The December 2020 final rule removed the phrase “allegedly committed by the patient,” explaining that the phrase was included in previous rulemaking by error, and clarifying that a court has the authority to permit disclosure of confidential communications when the disclosure is necessary in connection with investigation or prosecution of an extremely serious crime that was allegedly committed by either a patient or an individual other than the patient.

Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act

On March 27, 2020, Congress enacted the CARES Act⁸³ to provide emergency assistance to individuals, families, and businesses affected by the COVID–19 pandemic. Section 3221 of the CARES Act, Confidentiality and Disclosure of Records Relating to Substance Use Disorder, substantially amended 42 U.S.C. 290dd–2 to more closely align Federal privacy standards applicable to part 2 records with the HIPAA and HITECH Act privacy standards, breach notification standards, and enforcement authorities that apply to PHI, among other modifications.

The requirements in 42 U.S.C. 290dd–2(b), (c), and (f), as amended by section 3221 of the CARES Act, with respect to patient consent and redisclosures of SUD records, now align more closely with HIPAA Privacy Rule provisions permitting uses and disclosures for TPO and establish certain patient rights with respect to their part 2 records consistent with provisions of the HITECH Act; restrict the use and disclosure of part 2 records in legal proceedings; and set civil and criminal penalties for

that is not a health care provider for continuity of care purposes? For example, can a health care provider refer a patient experiencing homelessness to a social services agency, such as a housing provider, when doing so may reveal that the basis for eligibility is related to mental health?” (Jan. 9, 2023), <https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html>.

⁸² 85 FR 80626 (Dec. 14, 2020).

⁸³ Public Law 116–136, 134 Stat. 281 (Mar. 27, 2020). Significant components of section 3221 are codified at 42 U.S.C. 290dd–2 as further detailed in this final rule.

⁶⁶ See 82 FR 6052, 6064.

⁶⁷ 82 FR 6052, 6054.

⁶⁸ See 83 FR 239, 241–242.

⁶⁹ *Id.* at 242.

⁷⁰ 83 FR 239, 240. See also 82 FR 5485, 5487 (Jan. 18, 2017).

⁷¹ 83 FR 239, 242.

⁷² 82 FR 6052, 6053.

⁷³ 83 FR 239, 242.

violations. Section 3221 also amended 42 U.S.C. 290dd–2(j) and (k) by adding HITECH Act breach notification requirements and new terms and definitions consistent with the HIPAA regulations and the HITECH Act, respectively. Finally, section 3221 requires the Department to modify the HIPAA NPP⁸⁴ requirements at 45 CFR 164.520 so that covered entities and part 2 programs provide notice to individuals regarding privacy practices related to part 2 records, including individuals' rights and uses and disclosures that are permitted or required without authorization.

Paragraph (b) of section 3221 (Disclosures to Covered Entities Consistent with HIPAA), adds a new paragraph (1) (Consent), to section 543 of the PHSA⁸⁵ and expands the ability of covered entities, business associates, and part 2 programs to use and disclose part 2 records for TPO. The text of section 3221(b) adding paragraph (1)(B) to 42 U.S.C. 290dd–2 states that once prior written consent of the patient has been obtained, those contents may be used or disclosed by a covered entity, business associate, or a program subject to 290dd–2 for the purposes of TPO as permitted by the HIPAA regulations. Any disclosed information may then be redisclosed in accordance with the HIPAA regulations.

To the extent that 42 U.S.C. 290dd–2(b)(1) now provides for a general written patient consent covering all future uses and disclosures for TPO “as permitted by the HIPAA regulations,” and expressly permits the redisclosure of part 2 records received for TPO “in accordance with the HIPAA regulations,” the Department believes this means the recipient redisclosing the records must be a covered entity, business associate, or part 2 program that has received part 2 records under a TPO consent. The Department's proposals throughout this final rule are premised on its reading of section 3221(b) as applying to redisclosures of part 2 records by covered entities, business associates, and part 2 programs, including those covered entities that are part 2 programs.

In addition to the provisions of section 3221 described above, paragraph (g) of section 3221, *Antidiscrimination*, adds a new provision (i)(1) to 42 U.S.C. 290dd–2 to prohibit discrimination against an individual based on their part 2 records in: (A) admission, access to, or

treatment for health care; (B) hiring, firing, or terms of employment, or receipt of worker's compensation; (C) the sale, rental, or continued rental of housing; (D) access to Federal, State, or local courts; or (E) access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.⁸⁶ Further, the new paragraph (i)(2) prohibits discrimination by any recipient of Federal funds against individuals based on their part 2 records.⁸⁷ As stated in the NPRM, the Department intends to implement the CARES Act antidiscrimination provisions in a separate rulemaking. However, we discuss below and briefly respond to comments we received on the NPRM concerning antidiscrimination and stigma issues.

III. Overview of Public Comments

A. General Discussion of Comments

The Department received approximately 220 comments on the NPRM. By a wide margin, most of the commenters represented organizations rather than individuals (87 percent versus 13 percent). Professional and trade associations, including medical professional associations, and patient, provider, or other advocacy organizations were the most represented, followed by organizations that could fall within multiple categories. Other commenters included hospitals and health care systems, state and local government agencies, health plans and managed care organizations, health IT vendors, and unaffiliated individuals. Among the 27 individual commenters, nearly a third stated that they had current or past experience as an SUD provider, health care administrator, or health IT or legal professional.

The specific issue mentioned most frequently in comments was the proposal to allow patients to sign a single consent form for all future uses and disclosures of their SUD records for TPO purposes. This was followed by the proposed consent requirements, regulatory definitions, protections for patients in investigations and proceedings against them, and requirements for intermediaries, in that order.

B. General Comments

Approximately 75 percent of commenters provided general views on the NPRM covering multiple issues, including the need for better or complete alignment with HIPAA,

concerns about erosion of privacy and the need for informed consent for disclosures, requests for Departmental guidance, and requests to better fund SUD treatment services and health IT technology for part 2 providers.

General Support for the Proposed Rule

Public comments showed strong general support for the NPRM, with nearly half voicing clear support and nearly one-third expressing support while offering suggestions for improvement. Comments in support of the proposed rule stated that the proposed changes would improve care coordination, support patient privacy, reduce data and information gaps between patients and providers, reduce the stigma around SUD treatment, and reduce costs.

A group of commenters supported the proposed changes but did not view the proposals as sufficient—they sought more comprehensive change, to essentially recreate a set of HIPAA standards for part 2 records.

General Opposition to the Proposed Rule

Some commenters that expressed opposition to the NPRM stressed the importance of privacy and the need for informed consent regarding the use and disclosure of SUD treatment information, particularly for the use of records in investigations and proceedings against a patient. Some SUD providers, medical professionals, trade associations, advocacy organizations, a mental health provider, and nearly all individual commenters urged the Department not to make changes to part 2, largely to maintain the existing privacy protections. One advocacy organization urged the Department to weigh the risk to patients of their data being used without their permission and their potential loss of privacy surrounding seeking treatment for SUD, against any potential benefits provided for providers by the new rule.

IV. Analysis and Response to Public Comments and Final Modifications

The discussion below provides a section-by-section description of the final rule and responds to comments received from the public in response to the 2022 NPRM. As the Department discussed in the NPRM, the CARES Act did not expressly require every proposal promulgated by the Department. Some of the Department's proposals were proposed to align the language of this regulation with that in the HIPAA Privacy Rule and to clarify already-existing part 2 permissions or restrictions.

⁸⁴ Section 3221(i) requires the Secretary to update 45 CFR 164.520, the HIPAA Privacy Rule requirements with respect to the HIPAA NPP.

⁸⁵ Paragraph (1) is codified at 42 U.S.C. 290dd–2(b).

⁸⁶ See sec. 3221(g) of the CARES Act.

⁸⁷ *Id.*

A. Effective and Compliance Dates

Proposed Rule

In the NPRM, the Department proposed to finalize an effective date for a final rule that would occur 60 days after publication, and a compliance date that would occur 22 months after the effective date. Taken together, the two dates would give entities two years after publication to finalize compliance measures. In the NPRM, we⁸⁸ stated “[e]ntities subject to a final rule would have until the compliance date to establish and implement policies and practices to achieve compliance.”⁸⁹ The Department proposed to provide the same compliance date for both the proposed modifications to 45 CFR 164.520, the HIPAA NPP provision, and the more extensive part 2 modifications.

The HIPAA regulations generally require covered entities and business associates to comply with new or modified standards or implementation specifications no later than 180 days from the effective date of any such standards or implementation specifications,⁹⁰ whereas the part 2 regulation does not contain a standard compliance period for regulatory changes.

However, as we explained in the NPRM, the proposed compliance period would allow part 2 programs to revise existing policies and practices, complete other implementation requirements, and train their workforce members on the changes, as well as minimize administrative burdens on entities subject to the HIPAA Privacy Rule.

We requested comment on the adequacy of the 22-month compliance period that follows the proposed effective date and any benefits or unintended adverse consequences for entities or individuals of a shorter or longer compliance period.

Comment

More than half of the commenters who addressed the timeline for compliance, including several providers, health plans, professional medical and trade associations, and HIE networks, expressed support or opined that the proposed dates were feasible. Some of these commenters believed changes could be implemented sooner. Several of these supportive commenters offered the opinion that compliance deadlines facilitate care coordination and therefore should not be unnecessarily delayed, but that the

Department should offer technical assistance leading up to the compliance deadline to assist entities in implementing these changes. Some commenters stated that the Department should make clear that covered entities and part 2 programs who wish to comply with new finalized provisions, such as permissively using and disclosing SUD records for TPO or using the new authorization form with a general designation, before the proposed timeline should be able to do so voluntarily.

Several commenters opined that the compliance timeline should be shortened. In general, these commenters stated that a shorter compliance timeline would more quickly facilitate improved care coordination for SUD patients and avoid extending the opioid crisis. A few of these commenters suggested that the gap in time between the effective date and compliance date would allow entities to “choose” whether to follow existing or revised regulations for a period of time, and thus impede interoperability. Others in this group of commenters suggested that the proposed compliance date was excessively long, demonstrated a lack of urgency by the Department for improving SUD data exchange and care for SUD patients, and would prolong the “misalignment” of privacy protections for different types of information. One of these commenters recommended an alternative 12-month timeline that would include the effective date with only 10 additional months for compliance. A few of these commenters further encouraged the Department to clarify that entities wishing to implement any regulatory changes before the proposed timelines could voluntarily do so.

Response

We appreciate the comments and clarify here that persons who are subject to the regulation and are able to voluntarily comply with regulatory provisions finalized in this rulemaking may do so at any time after the effective date. We also agree with the commenters who emphasized the important role that this rule will play in improving care coordination for patients experiencing addiction or other forms of SUD, and we acknowledge their concerns about timely implementation. As finalized, we believe the effective and compliance dates strike the right balance between incentivizing entities to come into compliance in a timely fashion, and granting them sufficient time to adjust policies, procedures, and, in some cases, technology to support new or revised regulations.

Comment

A few commenters expressed support for the proposed timelines but requested clarification about whether new finalized provisions would apply to records created prior to the compliance date of the final rule. These commenters urged the Department to apply modified requirements to part 2 records created prior to the compliance date of the final rule to avoid the burdensome task of separating records and applications for consent.

Response

The changes finalized in this rule will apply to records created prior to the final rule. We agree with commenters who stated that separating records by date of creation for differential treatment would be unduly burdensome.

Comment

Slightly less than half of the commenters about this topic, including medical associations, a technology vendor, HIE/HINs, state and local agencies, health plans, and professional provider organizations, suggested that the Department should either lengthen the compliance timeline or finalize the proposed compliance date but delay enforcement, or issue a compliance safe harbor beyond the compliance date. For example, one commenter suggested that the Department implement a two-year enforcement delay while a few other commenters suggested a three-year enforcement delay or two-year phased enforcement approach beyond the compliance date. Some commenters requested that the Department spend the time tolled by the enforcement delay to issue implementation guidance addressing the interaction of the Centers for Medicare & Medicaid Services (CMS) Interoperability Rule,⁹¹ HIPAA regulations, and 42 CFR part 2, or work with the IT vendor community to address data segmentation approaches.

A few state and local agencies opined that the 22-month compliance period following the effective date would not be adequate for communication, training, implementation, and monitoring of extensive SUD provider networks with varying delivery options. One of these agencies cited as an example the state of California where the Medicaid SUD service delivery system may include hundreds of county and contracted providers such that the burden of audits, deficiency findings, and corrective actions would be felt statewide. Another state agency commented that its state needed more

⁸⁸ In this final rule, “we” and “our” denote the Department.

⁸⁹ 87 FR 74216, 74218.

⁹⁰ See 45 CFR 160.105.

⁹¹ See 85 FR 25510 (May 1, 2020).

time to develop a means to track TPO disclosures and recommended a 60-month timeline after publication of the rule. Other alternative timelines suggested by commenters included a recommendation by a dental professional association to establish an effective date of no less than one year after publication of the final rule, and a compliance date of no less than one year after the effective date; an additional 12 months beyond the proposed 22-month compliance timeline to better accommodate new interoperability rules and a corresponding need by part 2 programs to update technology; or a 34-month period following the 60-day effective date period to grant part 2 programs greater time to implement changes in practice related to the rule, as well as additional time for questions and clarifications from the Department. Commenters also suggested that an enforcement delay include a delay in imposing civil monetary penalties or “safe harbor” protection for part 2 programs, providers, business associates, and covered entities acting in good faith.

Response

We disagree with commenters who suggested or recommended that the Department delay enforcement of a final part 2 rule beyond the proposed timeline. We also disagree that additional safe harbor protection for the entities that would be regulated under this rule is necessary or appropriate. Either an enforcement delay or an enforcement safe harbor (that would effectively extend the compliance timeline) would frustrate the timely implementation of the CARES Act amendments to meaningfully improve the ability of impacted entities to coordinate care for individuals experiencing SUD, as suggested by the many commenters who either agreed with the proposed effective and compliance dates or sought a shorter compliance timeline. The Department may provide further guidance on the CMS Interoperability Rule in relation to data segmentation issues, HIPAA, and part 2, but we do not believe that this should delay finalization of the modifications to the part 2 rule or compliance deadlines.

Comment

One commenter, a Tribal health board, recommended that Indian Health Service (IHS) and Tribal facilities using the existing IHS medical record system be exempted from compliance with part 2 until such time as IHS modernizes its electronic health record (EHR) system, projected for 2025. It further requested

that SAMHSA issue guidance for pharmacies utilizing and issuing electronic prescriptions through the Resource and Patient Management System (RPMS) EHR system, and associated redisclosures, in the context of an integrated pharmacy system with the full RPMS EHR.

Response

The timeline finalized here is consistent with this request. As explained, the two-month delay between publication and an effective date combined with a 22-month compliance deadline beyond the effective date grants entities two years after publication to comply. Absent extenuating circumstances that cause the Department to require compliance sooner, this final rule will require compliance no earlier than third quarter of calendar year 2025.

Comment

A few commenters representing HIE networks expressed support for the Department’s proposal to toll the date by which part 2 programs must comply with the proposed accounting of disclosures requirements at § 2.25 until the effective date of a final rule on a revised HIPAA accounting of disclosures standard at 45 CFR 164.528 to ensure the consistency with HIPAA.

Response

We appreciate these comments.

Comment

A few commenters recommended that the Department delay this rule in its entirety until other proposed HIPAA regulations are finalized to permit commenters to better assess interactions between the alignment and to reduce administrative burden, such as reviewing multiple proposed HIPAA NPP provisions.

Response

The Department is not finalizing the proposed HIPAA NPP provisions in this final rule, but plans to do so in a future HIPAA final rule. We intend to align compliance dates for any required changes to the HIPAA NPP and part 2 Patient Notice to enable covered entities to make such changes at the same time. We believe the two-year compliance timeline following publication of this rule provides adequate time to assess alignment implications between HIPAA and part 2 and adjust accordingly.

Final Dates

The final rule adopts the proposed effective date of 60 days after publication of this final rule, and the

proposed compliance date of 24 months after the publication of this final rule. We are also finalizing the proposed accounting of disclosure provision at § 2.25, but tolling the effective and compliance dates for that provision until such time as the Department finalizes a revised provision in HIPAA at 45 CFR 164.528.

B. Substantive Proposals and Responses to Comments

Section 2.1—Statutory Authority for Confidentiality of Substance Use Disorder Patient Records

Proposed Rule

Section 2.1 describes the statutory authority vested in 42 U.S.C. 290dd–2(g) to prescribe implementing regulations. The Department proposed to revise § 2.1 to more closely align this section with the statutory text of 42 U.S.C. 290dd–2(g) and subsection 290dd–2(b)(2)(C) related to the issuance of court orders authorizing disclosures of part 2 records.

Comment

A health plan commenter expressed support for this language alignment and that the specific references to authorized disclosures pursuant to court order will assist part 2 programs in their compliance efforts. A state agency said that these changes to part 2 will affect its Medicaid system and Prepaid Inpatient Health Plans. Compliance is further required for State licensed narcotic treatment facilities and residential alcohol and drug treatment facilities.

Response

We appreciate these comments.

Final Rule

The final rule adopts the proposed changes to this section without further modification.

Section 2.2—Purpose and Effect

Proposed Rule

Section 2.2 establishes the purpose and effect of regulations imposed in this part upon the use and disclosure of part 2 records. The Department proposed to amend paragraph (b) of this section to reflect that § 2.2(b) compels disclosures to the Secretary that are necessary for enforcement of this rule, using language adapted from the HIPAA Privacy Rule at 45 CFR 164.502(a)(2)(ii). In the NPRM, the Department stated that the regulations do not require use or disclosure under any circumstance other than when disclosure is required by the Secretary to investigate or determine a person’s compliance with

this part.⁹² The Department also proposed to add a new paragraph (b)(3) to this section to clarify that nothing in this rule should be construed to limit a patient's right to request restrictions on use of records for TPO or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the HIPAA Privacy Rule. The Department specifically stated that the "regulations in this part are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out." ⁹³

Comment

A commenter said that it is logical for disclosures to the Secretary under § 2.2 to be consistent with analogous disclosures under HIPAA. Regarding the proposed modification to § 2.2(b)(1) to provide that the regulations generally do not require the use and disclosure of part 2 records, except when disclosure is required by the Secretary, another commenter said that it would be more logical and appropriate to treat part 2 records as HIPAA-covered records. The commenter believed that continued stigmatization of the diagnoses treated by part 2 facilities is a barrier to treatment and creates a two-tiered approach to use and disclosure that provides no meaningful benefit to patients.

Response

We appreciate these comments and have finalized this section as noted below. We believe our changes align part 2 more closely with HIPAA while also acknowledging changes to 42 U.S.C. 290dd–2, as amended by section 3221 of the CARES Act, which continue to provide additional protection for part 2 records, especially in legal proceedings against a patient. This section is needed to prevent harm to patients from stigma and discrimination consistent with the intent of part 2 and the CARES Act, including newly added statutory antidiscrimination requirements (42 U.S.C. 290dd–2(i)).

Comment

A SUD professional association discussed stigma and discrimination to which SUD patients are subject and asked that any discussion of proposed changes in the NPRM first begin with the context of why these protections exist. Citing to § 2.2(b)(2), the association noted that there are a number of adverse impacts to which patients are vulnerable including those

related to: criminal justice, health care, housing, life insurance coverage, loans, employment, licensure, and other intentional or passive discrimination against patients. A psychiatric hospital said that, under current § 2.2(b)(2), the purpose of the substance use disorder confidentiality protections is to encourage care without fear of stigma-related adverse impacts, not to block access to it for patients.

Response

We have long emphasized and agree with commenters that one primary purpose of the part 2 regulations is to, as the 1987 rule stated, ensure "that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment." ⁹⁴ The final rule continues to emphasize, including in this section, that most uses and disclosures allowed under part 2 are permissive and not mandatory. The final rule adds that disclosure may be required "when disclosure is required by the Secretary to investigate or determine a person's compliance with this part pursuant to § 2.3(c)." Likewise, a court order with a subpoena or similar legal mandate may compel disclosure of part 2 records, as explained in § 2.61, Legal effect of order.⁹⁵

Comment

A commenter believed the Department's proposal to add a new paragraph (b)(3) to § 2.2 to provide that nothing in this part shall be construed to limit a patient's right to request restrictions on use of records for TPO or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the HIPAA Privacy Rule appears consistent with patients' rights requirements under HIPAA and is a logical clarification.

Response

We appreciate the comment on our proposed changes which are finalized here.

⁹⁴ 52 FR 21796, 21805.

⁹⁵ Section 2.61(a) provides that court orders entered under this subpart are "unique" and only issued to authorize a disclosure or use, and not "compel" disclosure. It further provides "A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under the regulations in this part." Under the HIPAA Privacy Rule, a disclosure pursuant to such a court order, but without an accompanying subpoena, would not constitute a disclosure required by law as that term is defined at 45 CFR 164.103.

Final Rule

The final rule adopts all changes to § 2.2 as proposed, without further modification.

Section 2.3—Civil and Criminal Penalties for Violations

Proposed Rule

Section 2.3 of 42 CFR part 2 currently requires that any person who violates any provision of the part 2 regulations be criminally fined in accordance with title 18 U.S.C. The Department proposed multiple changes to this section to implement the new authority granted in section 3221(f) of the CARES Act as applied in 42 U.S.C. 290dd–2(f) so that sections 1176 and 1177 of the Social Security Act apply to a part 2 program for a violation of 42 CFR part 2 in the same manner as they apply to a covered entity for a violation of part C of title XI of the Social Security Act (HIPAA Administrative Simplification).

The Department proposed to replace title 18 criminal enforcement with civil and criminal penalties under sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6), respectively, as implemented in the HIPAA Enforcement Rule.⁹⁶ The Department also proposed to rename § 2.3 as "Civil and criminal penalties for violations" and reorganize § 2.3 into paragraphs (a), (b), and (c). Proposed § 2.3(a) would incorporate the penalty provisions of 42 U.S.C. 290dd–2(f), which apply the civil and criminal penalties of sections 1176 and 1177 of the Social Security Act, respectively, to violations of part 2. Proposed changes and comments regarding paragraphs (a), (b), and (c) are discussed below.

Comment

We received comments concerning proposed revisions to § 2.3(a). A state agency requested clarification regarding the agencies authorized to enforce § 2.3. Given statutory changes made by the CARES Act, the commenter asked that the Department clarify which agencies are authorized to enforce part 2 pursuant to the proposed provision. This commenter opined that section 1176 of the Social Security Act authorizes the Secretary to impose penalties, the attorney general of a state to bring a civil action for statutory damages in certain circumstances, and OCR to use corrective action in cases where the person did not know of the violation involved. The commenter asked for confirmation that the Department is the Federal agency that is

⁹⁶ See 45 CFR part 160, subpart D (Imposition of Civil Money Penalties).

⁹² 87 FR 74216, 74226.

⁹³ 87 FR 74216, 74274.

authorized to enforce part 2 through civil penalties and further seeks clarification regarding whether the Department will act through OCR, SAMHSA, or another entity. The commenter also seeks clarification that the authorized state enforcement agency is the office of the attorney general. Additionally, section 1177 of the Social Security Act pertains to criminal penalties for knowing violations, but does not identify the specific agency charged with enforcement. The commenter seeks confirmation that under the proposed rule, the Federal Department of Justice (DOJ) has jurisdiction over enforcement of part 2 through criminal penalties.

Response

We appreciate requests for clarification on enforcement of part 2 as proposed and now finalized in this rule. As we have noted in previous rulemakings such as the “HIPAA Administrative Simplification: Enforcement” final rule “[u]nder sections 1176 and 1177 of the Act, 42 U.S.C. 1320d–5 and 6, these persons or organizations, collectively referred to as ‘covered entities,’ may be subject to CMPs and criminal penalties for violations of the HIPAA regulations. HHS enforces the CMPs under section 1176 of the Act, and [DOJ] enforces the criminal penalties under section 1177 of the Act.”⁹⁷ As part of the HITECH Act, state attorneys general may bring civil suits for violations of the HIPAA Privacy and Security Rules on behalf of state residents.⁹⁸ Under this final rule, alleged violators of part 2 are subject to the same penalties as HIPAA covered entities through sections 1176 and 1177 of the Social Security Act. The CARES Act granted enforcement authority to the Secretary for civil penalties and the Department will identify the enforcing agency before the compliance date of this final rule.

Comment

A state agency said that its state strongly opposes what it perceives as increasing the civil and criminal penalties described in § 2.3. Understanding the desire to ensure strong privacy protections are in place and that sanctions are necessary, the

agency opined that the current enforcement framework is adequate and increasing sanctions would be punitive rather than promoting compliance. Punitive sanctions should be brought only against those entities or individuals that failed to use due diligence and/or make every reasonable attempt to protect against unauthorized disclosure. Unintended unauthorized disclosures that result in no material patient harm should be treated as that—unintended disclosures that cause *de minimis* or no harm to patients. Increasing sanctions may have the unintended consequence of part 2 programs not sharing patient records even if the patient in fact desires disclosure.

Response

We appreciate this commenter’s concerns about part 2 enforcement and disagree that the sanctions for violations will be harsher than for violations of the HIPAA regulations. We note that 42 U.S.C. 290dd–2(f), as amended by section 3221(f) of the CARES Act, applies the provisions of sections 1176 and 1177 of the Social Security Act to a violation of 42 CFR part 2 in the same manner as they apply to a violation of part C of title XI of the Social Security Act. We are implementing these requirements in this final rule. As of the compliance date for this final rule, we anticipate taking a similar approach to addressing noncompliance under part 2 as for violations of HIPAA, ranging from voluntary compliance and corrective action to civil and criminal penalties.⁹⁹ Indeed, we are finalizing below § 2.3(c) which provides that the provisions of 45 CFR part 160, subparts C, D, and E, shall apply to noncompliance with this part with respect to records in the same manner as they apply to covered entities and business associates for violations of 45 CFR parts 160 and 164 with respect to PHI. As proposed, we are incorporating the entirety of 45 CFR part 160, subpart D, which includes the mitigating factors in 45 CFR 160.408 and the affirmative defenses in 45 CFR 160.410, to align part 2 enforcement with the HIPAA Enforcement Rule.

In contrast, prior to this final rule, all alleged part 2 violations were subject only to potential criminal penalties. Aligning part 2 and HIPAA enforcement approaches should make the enforcement process more straightforward for part 2 programs that

are covered entities because it offers the same mitigating factors for consideration in enforcement, such as the number of individuals affected by the violation; whether the violation caused physical, financial, or reputational harm to the individual or jeopardized an individual’s ability to obtain health care, the size of the covered entity or part 2 program; and whether the penalty would jeopardize the covered entity or part 2 program’s ability to continue doing business. This alignment also affords part 2 programs, including those that are covered entities, the same affirmative defenses to alleged noncompliance and generally prohibits the imposition of a civil money penalty for a violation that is not due to willful neglect and is corrected within 30 days of discovery.

Final Rule

We are finalizing § 2.3(a) to specify that under 42 U.S.C. 290dd–2(f), any person who violates any provision of this part shall be subject to the applicable penalties under sections 1176 and 1177 of the Social Security Act, 42 U.S.C. 1320d–5 and 1320d–6, as implemented in the HIPAA Enforcement Rule.

Section 2.3(b) Limitation on Criminal or Civil Liability

Proposed Rule

As noted in the NPRM, after consultation with DOJ, the Department proposed in § 2.3(b) to create a limitation on civil or criminal liability (“safe harbor”) for persons acting on behalf of investigative agencies when, in the course of investigating or prosecuting a part 2 program or other person holding part 2 records, such agencies or persons unknowingly receive part 2 records without first obtaining the requisite court order. The proposed safe harbor applies only in instances where records are obtained for the purposes of investigating a part 2 program or person holding the record, not a patient. Further, investigative agencies would be required to follow part 2 requirements for obtaining, using, and disclosing part 2 records as part of an investigation or prosecution, including requirements related to seeking a court order, filing protective orders, maintaining security for records, and ensuring that records obtained in program investigations are not used in legal actions against patients who are the subjects of the records.

This safe harbor would be available for uses or disclosures inconsistent with part 2 only when the person acting on behalf of an investigative agency acted

⁹⁷ 74 FR 56123, 56124 (Oct. 30, 2009). See also, U.S. Dep’t of Health and Human Servs., “How OCR Enforces the HIPAA Privacy & Security Rules” (June 7, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/how-ocr-enforces-the-hipaa-privacy-and-security-rules/index.html>.

⁹⁸ See U.S. Dep’t of Health and Human Servs., “State Attorneys General” (Dec. 21, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/state-attorneys-general/index.html>.

⁹⁹ See U.S. Dep’t of Health and Human Servs., “Enforcement Process” (Sept. 17, 2021), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/enforcement-process/index.html>; HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

with reasonable diligence to determine in advance whether part 2 applied to the records or part 2 program. Paragraph (b)(1) proposed to clarify what constitutes reasonable diligence in determining whether part 2 applies to a record or part 2 program before an investigative agency makes an investigative demand or places an undercover agent with the part 2 program or person holding the records. The Department proposed specifically that reasonable diligence under this provision would require acting within a reasonable period of time, but no more than 60 days prior to, the request for records or placement of an undercover agent or informant. As proposed, reasonable diligence would include taking the following actions to determine whether a health care practice or provider (where it is reasonable to believe that the practice or provider provides SUD diagnostic, treatment, or referral for treatment services) provides such services: (1) checking a prescription drug monitoring program (PDMP) in the state where the provider is located, if available and accessible to the agency under state law; or (2) checking the website or physical location of the provider.

In addition, § 2.3(b) as proposed was intended to require an investigative agency to meet any other applicable requirements within part 2 for any use or disclosure of the records that occurred, or would occur, after the investigative agency knew, or by exercising reasonable diligence would have known, that it received part 2 records. The Department also proposed amending §§ 2.66 and 2.67 to be consistent with and further implement these proposed changes in § 2.3.

Comment

A state agency that regulates health facilities expressed concern that statements made by HHS in the NPRM when describing the need for the safe harbor provision for investigative agencies might bring its authority to obtain part 2 records from health care facilities into question. The commenter explains that the Department's justification and interpretation of the need for a safe harbor provision could result in licensed health care facilities refusing to provide it with access to part 2 records until the state agency obtains a court order under subpart E. While the commenter appreciated the clarification provided by the Department in the NPRM ("[HHS] does not intend to modify the applicability of § 2.12 or § 2.53 for investigative agencies"), the commenter asked that § 2.3(b) affirm that investigative agencies will not be

required to demonstrate due diligence or obtain a court order if their access, use, and disclosure of part 2 records is covered by another exception to part 2, such as the audit and evaluation exception in § 2.53.

An academic medical center advocated for a narrower definition of "investigative agency" than proposed and expressed concern about applying the proposed limitation on liability to a broad category of agencies. Several other commenters also addressed in their comments the Department's proposed definition of "investigative agency" in § 2.11, suggesting inclusion of state, Tribal, or local agencies in this definition.

Response

We address comments on definitions below in § 2.11, including concerns about potential unintended adverse consequences of including "supervisory" agencies in the definition of "investigative agency". We believe that the definition of "investigative agency", combined with the safe harbor (and its reasonable diligence prerequisite) and the annual reporting requirement, provides an appropriate check on government access to records in the course of investigating a part 2 program or lawful holder in those situations where an agency discovers it has unknowingly obtained part 2 records. The safe harbor option to apply for a court order retroactively does not alter the criteria for a court to grant the order, which includes a finding that other means of obtaining the records were unavailable, would not be effective, or would yield incomplete information. Here, we also clarify that we do not intend, in § 2.3(b), to override the existing authority of investigative or oversight agencies to access records, without court order, when permitted under another section of this regulation. Rather than narrowing the definition, we also include, as some commenters requested, local, territorial, and Tribal investigative agencies in the final "investigative agency" definition because they have a role in investigations of part 2 programs.

Comment

Some SUD policy organizations and other commenters suggested that the Department should not include a safe harbor provision for investigative agencies, as this is not required by the CARES Act and is duplicative of existing protections such as qualified immunity. According to these commenters, the CARES Act does not require a limitation on civil or criminal liability for persons acting on behalf of

investigative agencies if they unknowingly receive part 2 records. Additionally, this provision is deleterious to the confidentiality of patients relying on part 2 protections of their records in seeking or receiving SUD treatment, further eroding the trust necessary between provider and patient for successful SUD treatment.

The commenters further addressed in their comments the reasonable diligence steps proposed to identify whether a provider is a covered part 2 program. Though the NPRM proposed that passing by a part 2 program to observe its operations or checking a PDMP is sufficient to determine whether a provider offers SUD services, many SUD providers are not required to share information with PDMPs, the commenters assert. One commenter suggested that PDMPs do not contain any information from part 2 programs that do not prescribe controlled substances to patients. Under § 2.36, opioid treatment programs (OTPs) may report methadone dispensing information to PDMPs, but only if the reporting is mandated by state law and authorized by a part 2-compliant consent form. The commenters asserted that more accurate verification methods exist, such as SAMHSA's online treatment locator or state treatment databases. If such a safe harbor provision is included, the standard for diligence must be made more explicit and subject to more rigorous standards, according to these commenters.

A legal advocacy organization commented that the safe harbor proposal fell outside the scope of the CARES Act and was an unnecessary change. It further commented that despite disclosing that it consulted with the DOJ, HHS failed to adequately explain why law enforcement merits special consideration for protection from liability or why HHS did not consult with civil rights organizations, legal and policy advocates, providers, or patients. In addition, this commenter opined that the proposed safe harbor provision had inadequate guardrails to protect privacy because the Department proposed a very low standard of reasonable diligence that the investigative agency would be required to show and insufficient examples of actions an investigative agency must take to identify whether a provider offered SUD treatment under part 2. The commenter also remarked that checking a state's PDMP website should not be sufficient to establish reasonable diligence since the majority of part 2 programs do not report information to PDMPs, and similarly, driving by a provider's physical location should not

be considered sufficient to establish reasonable diligence because many SUD providers preserve their patients' privacy by avoiding overt street signage or advertisements. This commenter suggested checking SAMHSA's online treatment locator or the state oversight agency's list of licensed and certified providers as better alternatives than those proposed in the NPRM.

An HIE association expressed concern that if patients believe that their information related to seeking SUD treatment or admitting continued SUD while in treatment could be disclosed to an investigative Federal Government agency, then they may forgo or stop receiving that treatment. SUD treatment and the part 2 patient records are some of the most sensitive pieces of a person's health record. The commenter suggested that it is important for OCR and SAMHSA to engage with patient advocacy organizations to understand the needs of patients to protect that privacy and ensure treatment is not foregone due to a fear of exposure. An individual commenter also recommended consultation by the Department with SUD patients and former patients.

Another group of commenters claimed that the proposed rule's new safe harbor provision in § 2.3 was unnecessary, overly broad, and was not required by the CARES Act. HHS should withdraw this proposed change, these commenters stated, or at least should include more accurate methods of how investigative agencies can determine a provider offers SUD services (and thus may be subject to part 2) such as consulting the SAMHSA online treatment locator.

An individual commenter viewed the proposed § 2.3(b) changes as stigmatizing because it would promote access to patients' records against their interests by law enforcement. Another individual commenter suggested the proposed safe harbor may create a chilling effect, dissuading people from seeking the SUD care and other kinds of health care, including prenatal care, that they need. One person in recovery said that the proposal's language is vague and open-ended, leaving room for interpretation and loopholes for fishing expeditions by law enforcement through patient records. This commenter further stated that while it is important that bad actor treatment centers or providers are held accountable, the solution should not sacrifice fundamental privacy rights of patients.

Another commenter recommended a bar against using the safe harbor provision without inquiring directly with the provider about whether part 2

applies. The organization has helped part 2 programs respond to hundreds of law enforcement requests for SUD treatment records. Based on its experience, many part 2 programs report that law enforcement officials are not familiar with part 2 and do not listen to program staff when they flag its requirements for law enforcement. The commenter stated that part 2 program staff have even been arrested and charged with obstruction for attempting to explain the Federal privacy law as a result of this lack of knowledge by law enforcement.

A county government expressed opposition to the Department's proposals in § 2.3, and relatedly in §§ 2.66 and 2.67. According to this commenter, the Department should consider that once information is received by an investigator, there is no way to undo the knowledge learned even if records are destroyed as required in §§ 2.66 and 2.67. Thus, the commenter concluded, the Department should not finalize the safe harbor.

Another county government, also expressing opposition to proposed changes in §§ 2.3 and 2.66, commented that it believes the creation of a safe harbor for improper use or disclosure of part 2 records by investigative agencies is contrary to the "fundamental policy goals" that support more stringent privacy protections for substance use treatment records under 42 CFR part 2. This commenter explained its view that patients remain fearful of legal repercussions for engaging in substance use and will be discouraged from seeking treatment if guardrails that protect information are lowered. This commenter further opined that creating a safe harbor for investigative agencies could have the unintended consequence of creating an incentive for investigative agencies to design document requests to technically meet the requirements of the safe harbor, with the hopes of providers turning over part 2 records to which the investigative agency would not otherwise have access. Furthermore, according to the commenter, the contents of part 2 records could conceivably be used as a basis for meeting the criteria for a court order to use or disclose these, or other part 2 records, under § 2.64. This commenter further recommended that investigators not be permitted to retroactively seek a court order to use or disclose part 2 record, and in no event should investigative agencies be able to use information from part 2 records that they did not have proper authority to receive as the basis for a retroactive court order for use of disclosure of part 2 records.

Response

As noted above and in response to comments, this final rule no longer considers the reasonable diligence requirement specific to the safe harbor to be met by checking the applicable PDMP. Instead, this rule in the regulatory text of § 2.3 provides that "reasonable diligence" means taking all of the following actions: searching for the practice or provider among the SUD treatment facilities in SAMHSA's online treatment locator; searching in a similar state database of treatment facilities where available; checking a practice or program's website, where available, or physical location; viewing the entity's Patient Notice or HIPAA NPP if it is available; and taking all these steps within no more than 60 days before requesting records or placing an undercover agent or informant.

SAMHSA's online treatment locator,¹⁰⁰ even if it does not include every SUD provider or may include outdated information for some providers, still is more inclusive than PDMPs. Generally, only SUD providers who prescribe controlled substances submit data to PDMPs while SAMHSA's online treatment locator also includes SUD providers who do not prescribe controlled substances. Further, we believe that requiring consultation of a PDMP by investigative agencies could unnecessarily increase exposure of patient records that are contained in a PDMP with the records of part 2 programs or lawful holders who are under investigation. The inherent risk of an unnecessary disclosure of patient records runs counter to the underlying intent to keep these records confidential. Finally, the SAMHSA online treatment locator uses existing Departmental resources and is readily available to the general public at no cost.¹⁰¹

As to the suggestion that checking state licensing information would be a better indicator of a program's part 2 status, the Department disagrees. Licensing may occur at the facility level,

¹⁰⁰ See Substance Abuse and Mental Health Servs. Admin., "FindTreatment.gov," <https://findtreatment.gov/>.

¹⁰¹ See Ned J. Presnall, Giulia Croce Butler, and Richard A. Grucza, "Consumer access to buprenorphine and methadone in certified community behavioral health centers: A secret shopper study," *Journal of Substance Abuse Treatment* (Apr. 29, 2022), [https://www.jsatjournal.com/article/S0740-5472\(22\)00070-8/fulltext](https://www.jsatjournal.com/article/S0740-5472(22)00070-8/fulltext); Cho-Hee Shrader, Ashly Westrick, Saskia R. Vos, et al., "Sociodemographic Correlates of Affordable Community Behavioral Health Treatment Facility Availability in Florida: A Cross-Sectional Study," *The Journal of Behavioral Health Services & Research* (Jan. 4, 2023), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9812544/>.

or separately by occupational specialty, which would require an investigative agency to scour several sources of information. Further, the definition of part 2 program is broader than that of licensed SUD treatment providers because it can include prevention programs, so the pool of licensed provider is overly narrow and does not address the requirements that a program “hold itself out” as providing SUD services or that it is in receipt of Federal assistance.

Regarding comments that HHS did not consult with civil rights organizations, legal and policy advocates, providers, or patients, we note that we received and reviewed comments submitted by individuals and advocacy and civil rights organizations as we are required to do as part of the rulemaking process. We also consulted with DOJ and other Federal agencies.

We also acknowledge and appreciate concerns among some individual commenters that this provision may further stigmatize people seeking SUD treatment. However, we believe the requirement to demonstrate reasonable diligence to determine part 2 status in the safe harbor along with the requirements in §§ 2.66 and 2.67 that prohibit use or disclosure of records against a patient in a criminal investigation or prosecution or in an application for a court order to obtain records for such purposes will help ensure and enhance patient privacy consistent with the purpose and intent of part 2 and 42 U.S.C. 290dd–2 as amended by the CARES Act. We will monitor implementation and take steps to address any unintended adverse consequences that may follow, particularly for patients because they are not the intended focus of these investigations.

The safe harbor is not required by the CARES Act; it is grounded in the Secretary’s general rulemaking authority for the confidentiality of SUD patient records under 42 U.S.C. 290dd–2(g) and is necessary to operationalize subpart E, particularly in the context of other health care investigations. For example, investigative agencies may inadvertently obtain records from part 2 programs in the course of their investigations under other laws such as Medicaid fraud regulations, Drug Enforcement Administration (DEA) regulations, and HIPAA, where the applicability of part 2 (and the court order requirement for program investigations) is not obvious. The safe harbor provision facilitates a pathway to conduct the investigation under the amended part 2 statute. Contrary to some views expressed by commenters, it may be inappropriate for

an investigative agency to directly discuss with or contact the provider about whether part 2 applies because this could apprise them of an investigation or potential use of an informant under subpart E. In contrast, reliance on a publicly available directory, a HIPAA NPP, or Patient Notice offers neutral sources to alert agencies to the potential applicability of part 2.

Comment

A health care system commented that an investigative agency should have ample and sufficient notice that it may receive or come into contact with SUD records in the course of investigating or prosecuting a part 2 program. However, depending on the requirements or standards to be met, the commenter stated that it may be more expedient for an investigating agency to rely on the safe harbor after it comes into contact with part 2 records. As a result, investigative agencies might intentionally bypass the requirement to obtain consent or a court order and decide instead to avail themselves of the safe harbor after disclosure. In addition, the commenter asserted that the good faith standard could easily become diluted and might permit an investigator to hide behind the safe harbor when their conduct is the result of ignorance or an error in judgment. The commenter also expressed concern that the good faith standard would allow for a spectrum of interpretations and different courts may apply the standard differently, leading to inconsistent results; as such, it would be important for the Department to audit and monitor the use of the safe harbor to ensure it is being used appropriately.

An individual commenter asserted that expanding the reach of the CARES Act¹⁰² to create safe harbors for the criminal justice communities for violations of part 2 is beyond the intent of Congress, noting that the CARES Act does not require the creation of a limitation on civil or criminal liability for persons acting on behalf of investigative agencies if they unknowingly receive part 2 records. This commenter expressed concern that creating a limitation on civil or criminal liability under § 2.3 of 42 CFR part 2 or a good faith exception under the proposed new paragraph under § 2.66(a)(3) of 42 CFR part 2 would “encourage lax investigative actions on the part of an investigative agency.” The commenter believed that investigative agencies should continue to be required to seek an authorization from a court to

use or disclose any records implicated by part 2 protections because admonishing an investigative agency to cease using or disclosing part 2 records after the fact would in practice give the investigative agency license to screen and review part 2 records. This commenter also said that the good faith standard of § 2.66(a)(3) would offer investigative agencies an “excuse” to receive and review part 2 records. This commenter also asserted that §§ 2.3 and 2.66(a)(3) and (b) should be eliminated from the final rule as not required by the CARES Act and inconsistent with the confidentiality of a patient relying on part 2 protections of their records in seeking or receiving SUD treatment.

Another commenter argued that the limitation of liability would not negatively affect a patient’s access to SUD treatment but might “influence the investigative agency to be cavalier in obtaining the appropriate [consent or court order] if they are aware that its liability will be limited.” This commenter further opined that the annual reporting to the Secretary could serve as an important way to audit the use of the safe harbor this protection, and the limitation of liability may support an investigative agency’s ability to investigate a program, which could increase the quality of care.

Response

We believe that some commenters misunderstand the process of investigating a health care provider and we disagree that an investigator would always know before seeking records that a provider is subject to part 2. In many instances, an investigation is focused on the use of public money such as Medicaid or Medicare claims and reimbursement, and the focus is not on whether a provider is treating SUDs. Regarding the good faith standard as we explain below, we believe the phrase is generally understood to mean acting consistent with both the text and intent of the statute and part 2 regulations.

We believe that the operation of this provision is clear in the event a finding of good faith is not met. First, a lack of good faith could result in the imposition of HIPAA/HITECH Act penalties under 42 U.S.C. 290dd–2, as amended, if investigators are found to have acted in bad faith in obtaining the part 2 records. Second, in §§ 2.66 and 2.67, a finding of good faith is necessary to trigger the ability of the agency to apply for a court order to use records that were previously obtained.

We also disagree that this provision will encourage lax investigative actions or prompt agencies to “game” the regulations to improperly obtain

¹⁰² See sec. 3221(i)(1) of the CARES Act.

records. First, the manner in which agencies obtain records will be considered by a court as part of the court order process. Second, while the safe harbor operates as a limitation on civil and criminal liability under 42 U.S.C. 290dd–2(f), it does not provide absolute immunity under Federal or state law should an agency or person knowingly obtain records improperly or under false pretenses. For example, it would be improper to knowingly obtain records without following the required procedures for the type of request, or under false pretenses.

We agree with the sentiment that the reporting requirement in § 2.68 will serve as a useful tool to help monitor the appropriateness of investigative agencies' reliance on the regulatory safe harbor. We also appreciate the view that facilitating appropriate investigations will play an important role in ensuring the quality of care delivered by part 2 programs.

Comment

An SUD provider said that this safe harbor essentially could establish a loophole for investigative agencies to obtain part 2 records without following part 2 requirements, and thus adversely affect patient privacy. This commenter believed that the proposed rule attempted to justify the safe harbor by addressing the increased liability due to added penalties for violations of part 2, the need to prosecute bad actors, and public safety. However, this justification was misplaced, according to this commenter, and the safe harbor might only reduce important protections that limit investigative agencies' ability to obtain protected records. By replacing the required elements in place to protect the privacy of patients with a loosely defined reasonable diligence standard, the proposed rule would only increase the chances of investigative agencies unknowingly receiving part 2 records, according to this commenter. The proposed reasonable diligence standard provides investigative agencies with two options to determine part 2 application on a provider both of which the commenter views as insufficient. Ultimately, these proposed reasonable diligence standards can be easily bypassed as a way to obtain records without the requisite requirements. The organization expressed the belief that if a reasonable diligence standard remains in place, the Department should impose more stringent requirements under this standard, such as obtaining a copy of a provider's HIPAA NPP to determine part 2 applicability or comparable requirement.

Response

We acknowledge this commenter's concerns. As noted in this final rule at § 2.3, we are revising the proposed "reasonable diligence" standard to mean taking all of the following actions: searching for the practice or provider among the SUD treatment facilities in SAMHSA's online treatment locator; searching in a similar state database of treatment facilities where available; checking a practice or program's website, where available, or its physical location; viewing the entity's Patient Notice or HIPAA NPP if it is available; and taking all these steps within no more than 60 days before requesting records or placing an undercover agent or informant. We are requiring these reasonable diligence steps to be taken in response to commenters' concerns about the effects of the safe harbor on patient privacy and their specific recommendations for strengthening those steps. Importantly, an investigative agency could be subject to penalties under the CARES Act enforcement provisions if it does not take all of the steps in the required time frame as necessary to qualify for the protection afforded by the safe harbor. Finally, as discussed above, the reporting requirement to the Secretary will play an important role in ensuring transparency. After this rule is finalized, the Department intends to make use of such reports to monitor compliance with these requirements and work to educate patients, providers, investigative agencies and others about these provisions.

Comment

An individual commenter expressed concern about what they characterized as a broad swath of potential agencies that conduct activities covered by the term "investigation." The commenter opined that the types of agencies that conduct investigations are broad and many have repeatedly demonstrated their lack of prioritization of patient privacy and personal rights. The commenter believed that the Department outlines reasonable minimums including access controls, requesting and maintaining the minimum data required, and taking the most basic steps to determine if staff should or could access patient data before doing so, as well as obtaining the legally required permissions to lawfully receive such data. However, inability to follow these most basic guidelines does not support reducing liability, the commenter asserted, suggesting that the reasonable steps the Department describes in § 2.3 should be required for

investigative agencies to receive any PHI or part 2 records or to deploy an informant.

An anonymous commenter alleged that parole officers in their state frequently violate part 2 by making notes in an automated system redisclosing part 2 information from community providers. Until there is a regulatory and investigative agency invested in ensuring strict adherence to this regulation, the commenter said the Department should not ease up on the restrictions and access to SUD confidential information.

Response

We acknowledge that a broad range of agencies is encompassed within the definition of "investigative agency," and they have varying degrees of involvement with the provision of health care. The prerequisites for accessing part 2 records for audit and evaluation differ, intentionally, from the prerequisites for placing an informant within a program, although both may involve investigative agency review of part 2 records. The requirement to first obtain a court order before records are sought in a criminal investigation or prosecution is a much higher standard. While the safe harbor operates as a limitation on civil and criminal liability for agencies that have acted in good faith, it does not provide immunity under Federal or state law should an investigative agency knowingly obtain records improperly or under false pretenses. Further, this final rule establishes a right to file a complaint with the Secretary for violations of part 2 by, among others, lawful holders.

Comment

A medical professional association encouraged extending safe harbor protections to part 2 programs, providers, business associates, and covered entities acting in good faith for at least 34 months following the 60-day effective date period (36 total months). According to the commenter, this protection is essential to encourage providers to hold themselves out as SUD providers and other entities to support part 2 programs, which will be especially important as the health care system implements these new regulations. However, the commenter opposed the proposed the safe harbor for investigative agencies as written. According to this commenter, as written the proposed safe harbor could reduce access to care if part 2 programs or providers feel more at risk for acting in good faith than the investigative agencies that do not provide patient care.

Response

As discussed in the proposed rule, the effective date of a final rule will be 60 days after publication and the compliance date will be 24 months after the publication date. The Department acknowledges concerns about compliance and may provide additional guidance after the rule is finalized. We acknowledge requests by commenters to extend the safe harbor beyond investigative agencies to covered entities, health plans, HIEs/HINs, part 2 programs, APCDs, and others. However, we decline to make these requested changes because § 2.3 is specifically intended to operate in tandem with §§ 2.66 and 2.67 when investigative agencies unknowingly obtain part 2 records in the course of investigating or prosecuting a part 2 program and, as a result, fail to obtain the required court order in advance. We also believe that covered entities and business associates that are likely to receive part 2 records are routinely engaged in health care activities and are more likely to be aware when they are receiving such records.

Comment

A health IT vendor addressed our request for comment on whether to expand the limitation on civil or criminal liability for persons acting on behalf of investigative agencies to other entities. The commenter requested clarification on how the Department defines “unknowingly” when considering whether a safe harbor should be created for SUD providers that unknowingly hold part 2 records and unknowingly disclose them in violation of part 2.

Response

We have not developed a formal definition of “unknowingly;” however, the safe harbor for investigative agencies addresses situations where the recipient is unaware that records they have obtained contain information subject to part 2 although the agency first exercised reasonable diligence to determine if the disclosing entity was a part 2 program. The reasonable diligence expected of an SUD provider would be different in nature because such a provider uniquely possesses the information necessary to evaluate whether it is subject to this part, and consequently whether any patient records it creates are also subject to this part. We think it is more likely that the “unknowing” situation could occur when an entity other than a part 2 program receives records without the Notice to Accompany Disclosure and

rediscloses them in violation of this part because it is unaware that it possesses part 2 records. As we stated in the NPRM, we believe this scenario is addressed by the HITECH penalty tiers, so we are not expanding the safe harbor to other entities. Covered entities and business associates that are likely to receive part 2 records are routinely engaged in health care activities and are more likely to be aware that they are receiving such records. Further, the HITECH penalty tiers were designed to address privacy violations by covered entities and business associates.

Comment

Many commenters argued that the proposed safe harbor provisions should apply to entities beyond investigative agencies. The commenters included a medical association, a state Medicaid agency, a managed care organization, health care providers, HIEs, a state HIE association, and other professional and trade associations. The range of entities for which a safe harbor was recommended include the following: non-investigative agencies; covered entities; business associates; other SUD providers, facilities, and other providers generally who act in good faith and use reasonable diligence to determine whether records received/maintained are covered by part 2; health plans based on good faith redisclosures that comply with the HIPAA Privacy rule but not with the part 2 Rule; HIEs; SUD providers that are unaware of its practice designation as a part 2 provider; state Medicaid agency administering the Medicaid program; all payer claims databases (APCDs); part 2 programs; and lawful holders who, in good faith, unknowingly receive part 2 records and then unintentionally violate part 2 with respect to those records.

A county government argued that amending § 2.3 to contain a safe harbor provision for providers would better serve the policy goals of protecting patient privacy, while recognizing that health systems are moving toward integrating substance use treatment with other health conditions and behavioral health needs. Many part 2 programs provide integrated substance use and mental health treatment, and include providers who provide both mental health and substance use treatment or work in collaboration with mental health treatment providers. In these “dual diagnosis” programs, mental health providers may over time unknowingly generate and/or receive and possess records subject to part 2.

Another commenter, a professional association, urged that such a safe harbor should remain in place until

such time as there is an operationally viable means of providing the Notice to Accompany Disclosures of part 2 records in § 2.32. It should apply to HIPAA entities only if and to the extent that HHS does not, in the final rule, permit these entities to integrate these records with their existing patient records and treat the data as PHI which, the association asserted is the best approach from both patient care and operational perspectives.

Response

We acknowledge requests by commenters to extend the safe harbor beyond investigative agencies to covered entities, health plans, HIEs/HINs, part 2 programs, APCDs, and others. However, we decline to make these requested changes because § 2.3 is specifically intended to operate in tandem with §§ 2.66 and 2.67 when investigative agencies unknowingly obtain part 2 records in the course of investigating or prosecuting a part 2 program and, as a result, fail to obtain the required court order in advance. By contrast, §§ 2.12, 2.31, and 2.32, including the requirement in this final rule that each disclosure made with the patient’s written consent must be accompanied by a notice and a copy of the consent or a clear explanation of the scope of the consent, should be sufficient to inform recipients of part 2 records of the applicability of part 2 in circumstances that do not involve investigations or use of informants.

SUD providers, in particular, are obligated to know whether they are subject to part 2. In the event of an enforcement action against a lawful holder that involves an unknowing receipt or disclosure of part 2 records despite the lawful holder having exercised reasonable diligence, the Department will consider the facts and circumstances and make a determination as to whether the disclosure of part 2 records warrants an enforcement action against the lawful holder. This would include considering application of the “did not know” culpability tier for such violations.¹⁰³

Comment

A health information management association remarked that covered entities, lawful holders, and other recipients of SUD PHI are obligated to be aware of what information is being disclosed prior to disclosing it. Law enforcement requests for information

¹⁰³ See 45 CFR 160.404 (b)(2)(i) (the entity “did not know and, by exercising reasonable diligence, would not have known that [they] violated such provision[.]”). See also Social Security Act, sections 1176 and 1177.

should be clear to prevent inadvertent disclosures. According to the commenter, a court order, subpoena, or patient “authorization” should be necessary before obtaining SUD information. Under 45 CFR 164.512(e) criteria required for a valid court order and/or subpoena protects the SUD PHI. Disclosing SUD information before the correct protections are in place could result in the SUD information becoming discoverable through the Freedom of Information Act (FOIA).¹⁰⁴ In addition, once the information is disclosed the recipients cannot unsee or unknow the information, nor are mechanisms in place to properly return or destroy the information.

Response

Part 2, subpart E, requirements are distinct from the HIPAA Privacy Rule requirements at 45 CFR 164.512(e). We agree that it is important to engage with patients and patient organizations to ensure part 2 continues to bolster patient privacy and access to SUD treatment. SAMHSA provides funding to support the Center of Excellence for Protected Health Information Related to Behavioral Health¹⁰⁵ which does not provide legal advice but can help answer questions from providers and family members about HIPAA, part 2, and other behavioral health privacy requirements. The required report to the Secretary in § 2.68 will help the Department monitor investigations and prosecutions involving part 2 records. While in theory FOIA or similar state laws could apply to mistakenly released information, FOIA includes several exemptions and exclusions that could apply to withhold information from release in response to a request for such information, including FOIA Exemptions 3 (requires the withholding of information prohibited from disclosure by another Federal statute), 6 (protects certain information about an individual when disclosure would constitute a clearly unwarranted invasion of personal privacy), and 7 (protects certain records or information compiled for law enforcement purposes).¹⁰⁶ State health privacy laws or freedom of information laws may contain similar exemptions.¹⁰⁷

¹⁰⁴ Public Law 89–487, 80 Stat. 250 (July 4, 1966) (originally codified at 5 U.S.C. 1002; codified at 5 U.S.C. 552).

¹⁰⁵ See The Ctr. of Excellence for Protected Health Info., “About COE PHI,” <https://coephi.org/about-coe-phi/>.

¹⁰⁶ 5 U.S.C. 552(b)(3), (b)(6) & (b)(7).

¹⁰⁷ See, e.g., National Freedom of Info. Coal., “State Freedom of Information Laws,” <https://www.nfoic.org/state-freedom-of-information-laws/> and Seyfarth Shaw LLP, “50-State Survey of Health Care Information Privacy Laws” (July 15, 2021),

Final Rule

We are finalizing § 2.3(b) with the additional modifications discussed above in response to public comments and reorganizing for clarity. This final rule strengthens the safe harbor’s proposed reasonable diligence requirements in response to public comments that the proposed steps would be insufficient and provides that all of the specified actions must be initiated for the limitation on liability to apply. We clarify here that if any of the actions taken results in knowledge that a program or person holding records is subject to part 2, no further steps are required to further confirm that the program or person holding records is subject to part 2.

Section 2.3(c) Applying the HIPAA Enforcement Rule to Part 2 Violations

Proposed Rule

Proposed § 2.3(c) stated that the HIPAA Enforcement Rule shall apply to violations of part 2 in the same manner as they apply to covered entities and business associates for violations of part C of title XI of the Social Security Act and its implementing regulations with respect to PHI.^{108 109}

Comment

A state agency stated its view that if § 2.3(c) applies the various sanctions of HIPAA to part 2 programs regardless of whether the program is a HIPAA covered entity or business associate, the need to retain QSOs for part 2 programs that are not covered entities seems to be eliminated.

Response

We disagree that including this section obviates the need for QSOs, which we discuss below in § 2.11.

Final rule

We are finalizing § 2.3(c) with modifications changing references to “violations” to “noncompliance.” This minor change recognizes that the provisions of the HIPAA Enforcement Rule address not only penalties based on formal findings of violations but also

<https://www.seyfarth.com/news-insights/50-state-survey-of-health-care-information-privacy-laws.html>.

¹⁰⁸ See 45 CFR part 160, subpart C (Compliance and Investigations), D (Imposition of Civil Money Penalties), and E (Procedures for Hearings). See also sec. 13410 of the HITECH Act (codified at 42 U.S.C. 17929).

¹⁰⁹ This proposal would implement the required statutory framework establishing that civil and criminal penalties apply to violations of this part, as the Secretary exercises only civil enforcement authority. The DOJ has authority to impose criminal penalties where applicable. See 68 FR 18895, 18896 (Apr. 17, 2003).

many other aspects of the enforcement process, including procedures for receiving complaints and conducting investigations into alleged or potential noncompliance, which could result in informal resolution without a formal finding of a violation.

Section 2.4—Complaints of Noncompliance

Proposed Rule

The Department proposed to change the existing language of paragraphs (a) and (b) of § 2.4 which provide that reports of violations of the part 2 regulations may be directed to the U.S. Attorney for the judicial district in which the violation occurs and reports of any violation by an OTP may be directed to the U.S. Attorney and also to SAMHSA. Section 290dd–2(f) of 42 U.S.C., as amended by section 3221(f) of the CARES Act, grants civil enforcement authority to the Department, which currently exercises its HIPAA enforcement authority under section 1176 of the Social Security Act in accordance with the HIPAA Enforcement Rule. To implement these changes, the Department proposed to re-title the heading to this section by replacing “Reports of violations” with “Complaints of noncompliance,” and to replace the existing provisions about directing reports of part 2 violations to the U.S. Attorney’s Office and to SAMHSA with provisions about directing complaints of potential violations to a part 2 program. The Department noted that SAMHSA continues to oversee OTP accreditation and certification and therefore may receive reports of alleged violations by OTPs of Federal opioid treatment standards, including privacy and confidentiality requirements.

The Department proposed to add § 2.4(a) to require a part 2 program to have a process to receive complaints concerning a program’s compliance with the part 2 regulations. Proposed § 2.4(b) provided that a part 2 program may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any patient for the exercise of any right established, or for participation in any process provided for in part 2, including the filing of a complaint. The Department also proposed to add § 2.4(c) to prohibit a part 2 program from requiring patients to waive their right to file a complaint as a condition of the provision of treatment, payment, enrollment, or eligibility for any program subject to part 2.

Comment

Commenters generally supported the Department's proposal to establish a complaint process under § 2.4 that aligns with HIPAA and ensures part 2 programs would not retaliate against patients who filed a complaint or condition treatment or receipt of services on a patient's waiving any rights to file a complaint. Commenters advocated for part 2 patients being protected against potential discrimination, such as job loss, that may occur following improper disclosures of their treatment records. They further suggested that this provision aligns with the HIPAA Privacy Rule and thus will help to reduce administrative burdens. For example, covered entities can use their existing Privacy Offices and processes to oversee both part 2 and HIPAA compliance. Commenters also believed that application of the HIPAA Breach Notification Rule and the HIPAA Enforcement Rule will further help to protect part 2 patients. Additionally, commenters supported the inclusion of business associates and covered entities within the scope of this section.

Response

We appreciate the comments for the proposed changes to align part 2 with HIPAA Privacy Rule provisions concerning complaints. Patients with SUD continue to experience the effects of stigma and discrimination, one reason why privacy protections as established in this regulation remain important.¹¹⁰ We agree that aligning part 2 and HIPAA requirements may reduce administrative burdens.

Comment

One commenter expressed concern about enhanced penalties, which it characterized as potentially punitive and best reserved for those who fail to exercise due diligence. Such penalties may deter part 2 programs from sharing part 2 information, this commenter asserted. Other commenters similarly noted what they viewed as potential

deterrent effects of penalties provided for in this regulation on information sharing. A commenter urged reduced penalties for unintentional disclosures by part 2 programs as they may require time and assistance to comply with these regulations. Another commenter urged that clinicians should not be held liable for unintentional disclosures of part 2 records by part 2 programs which may need additional time and technical assistance to comply with these updated regulations in accordance with this regulation.

By contrast, another commenter urged strict enforcement of this provision including penalties for both negligent and intentional breaches. The commenter recommended enforcement by states' attorneys general and a private right of action for complainants under part 2 if states' attorneys general do not pursue enforcement.

Response

Existing part 2 language imposes a criminal penalty for violations.¹¹¹ Section 3221(f) of the CARES Act (codified at 42 U.S.C. 290dd–2(f)) requires the Department to apply the provisions of sections 1176 and 1177 of the Social Security Act to a part 2 program for a violation of 42 CFR part 2 in the same manner as they apply to a covered entity for a violation of part C of title XI of the Social Security Act. Accordingly, the Department proposed to replace title 18 U.S.C. criminal enforcement in the current regulation with civil and criminal penalties under sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6), respectively, as implemented in the HIPAA Enforcement Rule.¹¹² Under the HIPAA Enforcement Rule, criminal violations fall within the purview of DOJ. Historically, commenters have noted that enforcement of penalties concerning alleged part 2 violations has been limited.¹¹³ By aligning part 2 requirements in this final rule with current HIPAA provisions, part 2 programs now will be subject to an enforcement approach that is consistent with that for HIPAA-regulated health

care providers, thereby reducing administrative burdens for part 2 programs that are also HIPAA-covered entities. As some commenters suggested, this will also enable staff within HIPAA and part 2-regulated entities to more effectively collaborate given additional alignment of part 2 and HIPAA regulatory provisions.

Therefore, it is unlikely that part 2 programs will experience an adverse impact beyond that which in general applies to covered entities under HIPAA. As the Department has explained elsewhere, alleged unintentional violations are often resolved with covered entities through voluntary compliance or corrective action.¹¹⁴

Knowing or intentional violations of HIPAA may be referred to DOJ for a criminal investigation. As noted in the NPRM, criminal penalties may be imposed by DOJ for certain violations under 42 U.S.C. 1320d–6. After publication of this final rule, the Department may provide additional guidance specific to part 2; however, we anticipate that many entities now will be more comfortable appropriately sharing information and developing plans to mitigate risks of part 2 and HIPAA violations because the HIPAA and part 2 complaint provisions are now better aligned.¹¹⁵

Section 1176 of the Social Security Act, (codified at 42 U.S.C. 1320d–5), also provides for enforcement by states' attorneys general in the form of a civil action. The reference to this statutory provision in § 2.3 encompasses this avenue of enforcement.

Although the HIPAA and HITECH penalties do not provide a private right of action for privacy violations, as discussed elsewhere in this preamble, in this final rule we provide a right for a person to file a complaint to the Secretary for an alleged violation by a part 2 program, covered entity, business associate, qualified service organization, or other lawful holder of part 2 records. While a person may file a complaint to the Secretary, part 2 programs also must establish a process for the program to directly receive complaints. The right to file a complaint directly with the Secretary for an alleged violation is analogous to a similar provision within the HIPAA Privacy Rule.¹¹⁶ Although

¹¹⁰ See, e.g., Lars Garpenhag, Disa Dahlman, "Perceived healthcare stigma among patients in opioid substitution treatment: a qualitative study," Substance Abuse Treatment, Prevention, and Policy (Oct. 26, 2021), <https://pubmed.ncbi.nlm.nih.gov/34702338/>; Janet Zwick, Hannah Appleseth, Stephan Arndt, "Stigma: how it affects the substance use disorder patient," Substance Abuse Treatment, Prevention, and Policy (July 27, 2020), <https://pubmed.ncbi.nlm.nih.gov/32718328/>; Richard Bottner, Christopher Moriates and Matthew Stefanko, "Stigma is killing people with substance use disorders. Health care providers need to rid themselves of it," STAT News (Oct. 2, 2020), <https://www.statnews.com/2020/10/02/stigma-is-killing-people-with-substance-use-disorders-health-care-providers-need-to-rid-themselves-of-it/>.

¹¹¹ 42 CFR 2.3 (Criminal penalty for violation).

¹¹² HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

¹¹³ See Kimberly Johnson, "COVID-19: Isolating the Problems in Privacy Protection for Individuals with Substance Use Disorder," University of Chicago Legal Forum (May 1, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3837955; Substance Abuse and Mental Health Servs. Admin., "Substance Abuse Confidentiality Regulations; Frequently Asked Questions" (July 24, 2023), <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>.

¹¹⁴ See "Enforcement Process," *supra* note 99; HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

¹¹⁵ See U.S. Dep't of Health and Human Servs., "Guidance on Risk Analysis," (July 22, 2019), <https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html>.

¹¹⁶ 45 CFR 160.306.

the right to file a complaint to the Secretary for an alleged violation of part 2 was not included in the proposed text of § 2.4, it was included in the required statements for the Patient Notice.

Adding the language to § 2.4 is a logical outgrowth of the NPRM and a response to public comments received.

Comment

One commenter asked for a clarification of what is considered an “adverse action” for the purposes of this section. Other commenters requested clarification from the Department that acting on a complaint that was held in abeyance after a patient exercises their right to withdraw consent would not be viewed as retaliation.

Response

In the NPRM the Department referred to a prohibition on “taking adverse action against patients who file complaints.” This prohibition is broadly similar to that which exists within HIPAA in 45 CFR 160.316 and 164.530. The Department has described “adverse actions” as those that may constitute intimidation or retaliation, such as suspending someone’s participation in a program.¹¹⁷ We are not clear what the commenter means in referring to taking action on a complaint that was held in abeyance after a patient exercises their right to withdraw consent not being viewed as retaliation. However, a complaint can be withdrawn by the filer.¹¹⁸ Health care entities can likewise take steps to investigate complaints internally and OCR has developed tools and resources to support HIPAA compliance.¹¹⁹

Comment

Several commenters, including legal and SUD recovery advocacy organizations, urged the Department to include in the final rule provisions permitting a patient to complain directly to OCR or the Secretary, paralleling provisions in HIPAA. Another commenter asked about obligations of entities, such as medical licensing boards and physician health programs, and how a patient would report alleged violations by those entities.

¹¹⁷ 70 FR 20224, 20230 (Apr. 18, 2005); 71 FR 8389, 8399 (Feb. 16, 2006).

¹¹⁸ See U.S. Dep’t of Health and Human Servs., “Enforcement Highlights” (July 6, 2023), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html>.

¹¹⁹ See U.S. Dep’t of Health and Human Servs., “HIPAA Enforcement” (July 25, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html>.

Response

In response to public comments, we are adding a new provision to § 2.4 in this final rule to permit a person to file a complaint to the Secretary for a violation of this part by, among others, a lawful holder of part 2 records in the same manner as a person may file a complaint under 45 CFR 160.203 for a HIPAA violation. Specifically, we provide in § 2.4(b) that “[a] person may file a complaint to the Secretary for a violation of this part by a part 2 program, covered entity, business associate, qualified service organization, or other lawful holder” in the same manner as under HIPAA (45 CFR 160.306). By making this change, we are aligning part 2 with HIPAA and ensuring an adequate mechanism for review and disposition of complaints related to alleged part 2 violations. We are also adding a regulatory definition of lawful holder in this final rule at § 2.11. The Department will provide information about how to file complaints of alleged part 2 violations before the compliance date for the final rule.

Comment

A commenter asked whether the state, agency, or disclosing person would be penalized for a violation that results in the impermissible disclosure of records subject to HIPAA or part 2.

Response

Whether a party subject to part 2 is held accountable for a particular violation will depend on the facts and circumstances of the case. The Department has explained elsewhere that it will attempt to resolve enforcement actions through voluntary compliance, corrective action, and/or a resolution agreement, and we anticipate that applying the HIPAA Enforcement Rule framework to part 2 will have similar results.¹²⁰ Further, lawful holders are prohibited from using and disclosing records in proceedings against a patient absent written consent or a court order. In the case of an improper disclosure by a part 2 program employee, the part 2 program would likely be provided with notice of an investigation and the investigator would review whether the program had policies and procedures in place and whether those were followed in its handling of the improper disclosure. An entity’s compliance officer can help ensure breaches are properly investigated and reported to the

¹²⁰ See “How OCR Enforces the HIPAA Privacy & Security Rules,” *supra* note 97.

Department,¹²¹ and has responsibilities to develop and implement a compliance plan.

Comment

A commenter asked for clarification that penalties would not be concurrently imposed under both HIPAA and part 2 for the same alleged violation(s).

Response

HIPAA and part 2 regulations stem from different statutory authorities and are different compliance regulations. With the CARES Act, Congress replaced the previous criminal penalties established for part 2 violations with a civil and criminal penalty structure imported from HITECH. Nothing in the CARES Act states that an entity that is subject to both regulatory schemes shall be subject to only one regulation or one regulation’s penalties. Therefore, an entity potentially remains subject to both regulations, including their provisions on penalties for violations.

What penalties could or would be imposed by the Department in a particular case, and under which statutes or regulations (HIPAA, HITECH, part 2, other regulations), remains a fact-specific inquiry. State law provisions also may apply concurrently with some part 2 and HIPAA requirements.¹²² Additionally, some aspects of part 2 or HIPAA violations may fall within the jurisdiction of other agencies such as SAMHSA (which continues to oversee accreditation of OTPs).¹²³

Comment

One commenter noted that some covered entities may not be part 2

¹²¹ See “What are the Duties of a HIPAA Compliance Officer?” The HIPAA Journal, <https://www.hipaajournal.com/duties-of-a-hipaa-compliance-officer/>; U.S. Dep’t of Health and Human Servs., “The HIPAA Privacy Rule”, <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>; U.S. Dep’t of Health and Human Servs., “Submitting Notice of a Breach to the Secretary” (Feb. 27, 2023), <https://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html>; U.S. Dep’t of Health and Human Servs., “Training Materials”, <https://www.hhs.gov/hipaa/for-professionals/training/index.html>.

¹²² See The Off. of the Nat’l Coordinator for Health Info. Techn. (ONC), “HIPAA versus State Laws” (Sept. 5, 2017), <https://www.healthit.gov/topic/hipaa-versus-state-laws>; Nat’l Ass’n of State Mental Health Program Dirs., “TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations,” (2016) <https://www.nasmhpd.org/content/tac-assessment-working-paper-2016-compilation-state-behavioral-health-patient-treatment>.

¹²³ See Substance Abuse and Mental Health Servs. Admin., “Certification of Opioid Treatment Programs (OTPs)” (July 24, 2023), <https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program>.

providers and urged HHS to ease the burden on such programs. Another urged that business associates be included within the scope of this section.

Response

We provide in § 2.4(b) that “[a] person may file a complaint to the Secretary for a violation of this part by a part 2 program, covered entity, business associate, qualified service organization, or other lawful holder in the same manner as a person may file a complaint under 45 CFR 160.306 for a violation of the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.” Thus, covered entities and business associates are included within the scope of this section. The compliance burdens for covered entities of receiving part 2 complaints can be minimized by using the same process they already have in place for receiving HIPAA complaints.

Comment

Commenters provided their views as to which agency or agencies should receive part 2-related complaints. One commenter requested that the regulation expressly identify the agency(ies) authorized to receive part 2 complaints from patients. The commenter suggested that complaints made to part 2 programs by patients can raise conflict of interest issues because the program is investigating its own or its staff’s alleged misconduct. The commenter further urged that the regulation identify specific agencies, such as OCR and SAMHSA, and state their obligation to investigate complaints received. Other commenters urged that OCR, rather than part 2 programs, receive complaints, that patients be permitted to complain directly of violations to OCR or that the Department clarify the various roles of OCR, SAMHSA, and other agencies. One commenter supported part 2 programs having a process to receive complaints but said these programs are understaffed and underfunded so they would need additional resources. A health system that is a part 2 program and a covered entity also supported part 2 programs developing a process to receive complaints. A county health department asked that § 2.4 be amended to include specific provisions about how and where patients can file their complaints with the HHS Secretary and the roles of HHS components in receiving and investigating complaints.

Response

In response to public comments, and as provided in the HIPAA regulations,

we are finalizing an additional modification to § 2.4 that was not included in this section but was proposed as a required statement of rights in the Patient Notice in § 2.22(b)(1)(vi). The intent of the enforcement provisions in § 2.4 was to create a process that mirrors that for HIPAA violations, but the Department inadvertently omitted from its proposed changes to this section an express right to complain to the Secretary. Analogous to 45 CFR 160.306, which permits the submission of complaints to the Secretary alleging noncompliance by covered entities with the HIPAA Privacy Rule,¹²⁴ we are providing in this final rule a right for a person to file a complaint to the Secretary for an alleged violation by a part 2 program, covered entity, business associate, qualified service organization, and other lawful holder of part 2 records. Part 2 programs also must establish a process for the program to receive complaints. A patient is not obliged to report an alleged violation either to the Secretary or part 2 program but may report to either or both. OCR has explained how HIPAA complaints are investigated, which may be instructive, but is not dispositive of how part 2 complaints will be handled.¹²⁵ We believe our changes are a logical outgrowth of the NPRM which provided an opportunity for public input and we are making these changes in response to public comments received. We also anticipate releasing information about the specific complaint process after publication of this final rule.

Comment

A commenter urged that the complaint process reflect the needs of those with limited English proficiency.

Response

Part 2 programs should be mindful that Federal civil rights laws require certain entities, including recipients of Federal financial assistance and public entities, to take appropriate steps. For instance, such entities must take steps to ensure that communications with individuals with disabilities are as

effective as communications with others, including by providing appropriate auxiliary aids and services where necessary.¹²⁶ In addition, recipients of Federal financial assistance must take reasonable steps to ensure meaningful access to their programs and activities for individuals with limited English proficiency, including through language assistance services when necessary.¹²⁷ The Department stated in the 2017 Part 2 Final Rule that materials such as consent forms “should be written clearly so that the patient can easily understand the form.”¹²⁸ The Department further stated that it “encourages part 2 programs to be sensitive to the cultural and linguistic composition of their patient population when considering whether the consent form should also be provided in a language(s) other than English (e.g., Spanish).”¹²⁹ Consistent with these legal requirements, the Department strongly encourages development of § 2.4 materials that are clear and reflect the needs of a program’s patient population.

Comment

Another commenter remarked that some covered entities may need technical assistance from the Department to establish complaint processes under this section.

Response

The Department has existing materials to support compliance with HIPAA and part 2.¹³⁰ SAMHSA supports a Center of Excellence for Protected Health Information Related to Behavioral Health that may provide educational

¹²⁶ See e.g., U.S. Dep’t of Health and Human Servs., “Effective Communication for Persons Who Are Deaf or Hard of Hearing” (June 16, 2017), <https://www.hhs.gov/civil-rights/for-individuals/disability/effective-communication/index.html>; U.S. Dep’t of Health and Human Servs., “Section 1557: Ensuring Effective Communication with and Accessibility for Individuals with Disabilities” (Aug. 25, 2016), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/fs-disability/index.html>.

¹²⁷ See U.S. Dep’t of Health and Human Servs., “Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons” (July 26, 2013), <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html>; U.S. Dep’t of Health and Human Servs., “Section 1557: Ensuring Meaningful Access for Individuals with Limited English Proficiency” (Aug. 25, 2016), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/fs-limited-english-proficiency/index.html>.

¹²⁸ 82 FR 6052, 6077.

¹²⁹ *Id.*

¹³⁰ See “How OCR Enforces the HIPAA Privacy & Security Rules,” *supra* note 97; “Substance Abuse Confidentiality Regulations; Frequently Asked Questions,” *supra* note 113.

¹²⁴ See U.S. Dep’t of Health and Human Servs., “Federal Register Notice of Addresses for Submission of HIPAA Health Information Privacy Complaints” (June 8, 2020), <https://www.hhs.gov/guidance/document/federal-register-notice-addresses-submission-hipaa-health-information-privacy-complaints>; U.S. Dep’t of Health and Human Servs., “Filing a Complaint” (Mar. 31, 2020), <https://www.hhs.gov/hipaa/filing-a-complaint/index.html>.

¹²⁵ See U.S. Dep’t of Health and Human Servs., “How to File a Health Information Privacy or Security Complaint” (Dec. 23, 2022), <https://www.hhs.gov/hipaa/filing-a-complaint/complaint-process/index.html>.

materials and technical assistance to providers, patients, family members, and others.¹³¹ The Department will consider what additional guidance, technical assistance, and engagement on these issues may be helpful for covered entities and the public after this regulation is finalized.

Comment

Other commenters emphasized that the Department may need additional funding and staff adequate to receive and investigate complaints and enforce these provisions. Another commenter similarly suggested that part 2 programs may need more resources to develop a complaint process, describing this as a “substantial burden” given part 2 program staff and funding challenges.

Response

With respect to the burden on programs to develop a complaint process, we believe that the two-year compliance timeline will provide programs with sufficient time to plan for complaint management. We have accounted for the burden associated with complaints in the RIA. The Department has requested that Congress provide additional funding to support part 2 compliance, enforcement, and other activities.¹³² OCR, SAMHSA, CMS, and the Office of the National Coordinator for Health Information Technology (ONC) have and will continue to collaborate to support EHRs and health IT within the behavioral health space.¹³³

Comment

Another commenter believed that programs may need time and support to adapt their information technology and EHRs, and urged SAMHSA to work with ONC to support such efforts.

Response

The Department has estimated the cost to the Department to implement this final rule and enforce part 2 and has included that in the RIA. It has also requested additional funding to support compliance, enforcement, and other activities.¹³⁴ The number of part 2 programs in relation to HIPAA covered entities and business associates is very

small, so the costs will not rise to the same level as for HIPAA implementation efforts. OCR, SAMHSA, CMS, and ONC have collaborated and will continue to collaborate to support EHRs and health IT within the behavioral health space.¹³⁵

Final Rule

We are finalizing this section as proposed in the NPRM and further modifying it by adding a new paragraph that provides a patient right to file a complaint directly with the Secretary for violations of part 2 by programs, covered entities, business associates, qualified service organizations, and other lawful holders.

As noted in the NPRM, these changes to § 2.4 will align part 2 with HIPAA Privacy Rule provisions concerning complaints. Section 2.4(a) is consistent with the administrative requirements in 45 CFR 164.530(d) (Standard: Complaints to the covered entity). Proposed § 2.4(c) would align with the HIPAA Privacy Rule provision at 45 CFR 164.530(g) (Standard: Refraining from intimidating or retaliatory acts). The proposed § 2.4(d) would be consistent with the HIPAA Privacy Rule provision at 45 CFR 164.530(h) (Standard: Waiver of rights). Thus, part 2 programs that are also covered entities already have these administrative requirements in place, but programs that are not covered entities would need to adopt new policies and procedures.

Section 2.11—Definitions

Proposed Rule

Section 2.11 includes definitions for key regulatory terms in 42 CFR part 2. The Department proposed to add thirteen defined regulatory terms and modify the definitions of ten existing terms. Nine of the new regulatory definitions proposed for incorporation into part 2 were required by section 3221(d) of the CARES Act: “Breach,” “Business associate,” “Covered entity,” “Health care operations,” “HIPAA regulations,” “Payment,” “Public health authority,” “Treatment,” and “Unsecured protected health information.” In each case, 42 U.S.C. 290dd–2(k), as amended by section 3221(d), requires that each term “has the same meaning given such term for purposes of the HIPAA regulations.”¹³⁶

Other proposed new or modified definitions included: “Informant,”

“Intermediary,” “Investigative agency,” “Part 2 program director,” “Patient,” “Person,” “Program,” “Qualified service organization,” “Records,” “Third-party payer,” “Treating provider relationship,” “Unsecured record,” and “Use.” Some of these terms and definitions were proposed by either referencing existing HIPAA regulatory terms in 45 CFR parts 160 and 164 in part based on changes required by the CARES Act. We also proposed changes for clarity and consistency in usage between the HIPAA and part 2 regulations and to operationalize other changes proposed in the NPRM.

In addition, the Department discussed three definitions—for “Lawful holder,” “Personal representative,” and “SUD counseling notes”—in requests for comments. The Department proposed each definition because it believed the definitions improve alignment of this regulation with HIPAA and support implementation efforts.

Further, we are finalizing a modified definition of “Patient identifying information” as an outgrowth of changes to the standard for de-identification of records in §§ 2.16, 2.52, and 2.54 that are being finalized in response to comments in the NPRM.

General Comment

Several commenters, including large provider organizations, health systems, and an employee benefits association, expressed general support for the Department’s approach to aligning the definitions for terms that would appear in both HIPAA and part 2. One large provider organization specifically commented that alignment of definitions within HIPAA and part 2 would reduce administrative burden for covered entities and part 2 providers by eliminating inconsistent terminology, duplicative policies (including overlapping workforce training requirements), and regulatory risk due to misinterpretation. An academic medical center recommended that the Department compare and incorporate any HIPAA definition, in their entirety, as applicable to part 2 programs which are also HIPAA covered entities.

General Response

We appreciate the comments. The Department undertook a careful analysis of definitions that, if incorporated, would result in the further alignment of this regulation with HIPAA, or that are required to operationalize required amendments to the regulations. Responses to specific comments about each proposed definition are discussed below.

¹³¹ See “About COE PHI,” *supra* note 105.

¹³² See U.S. Dep’t of Health and Human Servs., “Department of Health and Human Services, Fiscal Year 2024,” FY 2024 Budget Justification, General Department Management, Office for Civil Rights, at 255, <https://www.hhs.gov/sites/default/files/fy-2024-gdm-cj.pdf>.

¹³³ *Id.* See also, The Off. of the Nat’l Coordinator for Health Info. Tech. (ONC), “Behavioral Health,” <https://www.healthit.gov/topic/behavioral-health>.

¹³⁴ See “Department of Health and Human Services, Fiscal Year 2024,” *supra* note 132.

¹³⁵ See “Behavioral Health,” *supra* note 133.

¹³⁶ Section 3221(k) para. 5 incorporates the term HIPAA regulations and reads: “The term ‘HIPAA regulations’ has the same meaning given such term for purposes of parts 160 and 164 of title 45, Code of Federal Regulations.”

Breach

Section 290dd–2(k), as added by the CARES Act, required the Department to adopt the term “breach” in part 2 by reference to the definition in 45 CFR 164.402 of the HIPAA Breach Notification Rule. HIPAA defines “breach” as “the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E which compromises the security or privacy of the protected health information.” HIPAA also describes the circumstances that are considered a “breach” and explains that a breach is presumed to have occurred when an “acquisition, access, use, or disclosure” of PHI occurs in a manner not permitted under the HIPAA Privacy Rule unless a risk assessment shows a low probability that health information has been compromised.¹³⁷ To implement section 290dd–2(j) added by section 3221(h) of the CARES Act, which requires notification in case of a breach of part 2 records, we reference and incorporate the HIPAA breach notification provisions.

Comment

One legal services commenter requested clarification on the term “breach” and suggested that the Department amend the definition to expressly refer to the misuse of records in a manner not permitted under 42 CFR part 2 and that compromises the security or privacy of the part 2 record, instead of referring to PHI. A medical professionals association questioned whether the term “breach” could properly be applied to lawful holders, but this comment and other comments related to the application of breach notification provisions to lawful holders are addressed in the description of comments for § 2.16.

Response

We understand the request to expressly refer to part 2 records instead of PHI, but as explained above, we are applying the statutory definition that adopts the definition of “breach” in this regulation by reference to the HIPAA provision. We believe the discussion above makes clear that the definition should be applied to records under part 2 instead of PHI under HIPAA, and we further clarify that breach includes use and disclosure of part 2 records in a manner that is not permitted by part 2.

Final Rule

The final rule adopts the proposed definition of “breach” without modification.

Business Associate

Consistent with 42 U.S.C. 290dd–2(k), the Department proposed to adopt the same meaning of “business associate” as is used in the HIPAA regulations by incorporating the HIPAA definition codified at 45 CFR 160.103. Within HIPAA, a “business associate” generally describes a person who, for or on behalf of a covered entity and other than a workforce member of the covered entity, creates, receives, maintains, or transmits PHI for a function or activity regulated by HIPAA, or who provides services to the covered entity involving the disclosure of PHI from the covered entity or from another business associate of the covered entity to the person.¹³⁸

Comment

The Department received only supportive comments for its proposed adoption of the term “business associate” into part 2 and the proposed definition, as described above. In contrast, many commenters expressed concern about the Department’s proposal to incorporate business associates into the definition of “Qualified service organization” or how business associates relate to the proposed term “Intermediary,” and those comments are discussed in applicable definitional sections below.

Response

We appreciate the comments.

Final Rule

The final rule adopts the proposed definition of “business associate” without modification.

Covered Entity

Consistent with 42 U.S.C. 290dd–2(k), the Department proposed to adopt the same meaning of the term “Covered entity” as is used in the HIPAA regulations by incorporating the HIPAA definition codified at 45 CFR 160.103. Within HIPAA a “covered entity” means: (1) a health plan; (2) a health care clearinghouse; or (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by subchapter C of HIPAA, Administrative Data Standards and Related Requirements.

Comment

A large hospital system commented that it supported the inclusion of “health plan” as part of the definition of “covered entity” asserting that it would allow for more consistent sharing of information with its own health plan and for certain redisclosures of part 2 records in alignment with HIPAA.

Response

The HIPAA definition of “covered entity” has long included health plans. However, to the extent that the commenter may be referring to the narrowed definition of “third party payer,” which excludes health plans because they are already incorporated within the HIPAA definition of covered entities, we agree that the change could have the effect described by the commenter.

Final Rule

The final rule adopts the proposed definition of “covered entity” without modification.

Health Care Operations

Consistent with 42 U.S.C. 290dd–2(k), the Department proposed to adopt the same meaning of this term as is used in the HIPAA regulations by incorporating the HIPAA definition codified at 45 CFR 164.501. Within HIPAA, “health care operations” refer to a set of specified activities, described in six paragraphs, that are conducted by covered entities related to covered functions. Paragraphs (1) through (6) generally refer to quality assessment and improvement; assessing professional competency or qualifications; insurance; detecting and addressing fraud and abuse and conducting medical reviews; business planning and development; and business management and general administrative activities.

Comment

A provider group specifically supported adoption of the HIPAA definition of the term “health care operations” and its incorporation into this regulation. A large health plan recommended expanding the proposed definition to include care coordination and case management by health plans as proposed by the Department in the 2021 HIPAA Privacy Rule NPRM.¹³⁹ One individual, commenting anonymously, asserted that “public health” should be recognized as a health care operation to

¹³⁷ U.S. Dep’t of Health and Human Servs., “Breach Notification Rule” (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html>.

¹³⁸ U.S. Dep’t of Health and Human Servs., “Business Associates” (May 24, 2019), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html>.

¹³⁹ See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6472 (Jan. 21, 2021).

counter what it termed “legal activism” to re-define the term “life.”

Response

We appreciate the comments. The Department also notes that changing the HIPAA definition of “health care operations” is outside the scope of its authority for this rulemaking, and public comments submitted in response to the 2021 NPRM remain under consideration.

Final Rule

The final rule adopts the proposed definition of “health care operations” without modification.

HIPAA

Although not directed by statute, the Department proposed to add a definition of HIPAA that explicitly references the Health Insurance Portability and Accountability Act of 1996 as amended by the Privacy and Security provisions in subtitle D of title XIII of the 2009 HITECH Act. These provisions pertain specifically to the privacy, security, breach notification, and enforcement standards governing the use and disclosure of PHI, but exclude other components of the HIPAA statute, such as insurance portability, and other HIPAA regulatory standards, such as the standard electronic transactions regulation. The Department proposed this definition of “HIPAA” to make clear the specific components of the relevant statutes that would be incorporated into this part.

Comment

The Department did not receive any comments specific to its adoption of this definition.

Final Rule

The final rule adopts the proposed definition of “HIPAA” without modification.

HIPAA Regulations

The current part 2 rule does not define “HIPAA regulations.” Consistent with 42 U.S.C. 290dd–2(k), the Department proposed to adopt the same meaning of this term as is purposed for parts 160 and 164 of title 45 CFR, the regulatory provisions that codify the HIPAA Privacy, Security, Breach Notification, and Enforcement regulations (collectively referred to as “HIPAA regulations”). For purposes of this rulemaking, the term does not include Standard Unique Identifiers, Standard Electronic Transactions, and Code Sets, 42 CFR part 162.

Comment

The Department did not receive any specific comments, other than those already discussed above, concerning its proposed definition of this term.

Final Rule

The final rule adopts the proposed definition of “HIPAA regulations” without modification.

Informant

Part 2 currently states that an “informant” means an individual: (1) who is a patient or employee of a part 2 program or who becomes a patient or employee of a part 2 program at the request of a law enforcement agency or official; and (2) who at the request of a law enforcement agency or official observes one or more patients or employees of the part 2 program for the purpose of reporting the information obtained to the law enforcement agency or official. Within the definition of “informant,” the Department proposed to replace the term “individual” with the term “person” as is used in the HIPAA regulations. The Department believes that this change will foster alignment with HIPAA, avoid confusion with the definition of individual in HIPAA, and improve the public’s understanding of HIPAA and the part 2 rules.

Comment

As noted below, the Department received general support for its proposal to align the definition of “person” within part 2 with the HIPAA definition of “person” in 45 CFR 160.103. The Department did not receive other specific comments on “informant”.

Final Rule

The final rule adopts the proposed definition of “informant” without modification.

Intermediary

The current rule imposes requirements on intermediaries in § 2.13(d)(2) and special consent provisions in § 2.31(a)(4) without defining the term “intermediary.” Examples of an intermediary include, but are not limited to, a HIE, a research institution that is providing treatment, an ACO, or a care management organization. To improve understanding of the requirements for intermediaries, and to distinguish those requirements from the proposed accounting of disclosure requirements, the Department proposed to establish a definition of intermediary as “a person who has received records, under a general designation in a written patient

consent, for the purpose of disclosing the records to one or more of its member participants who has a treating provider relationship with the patient.”

Consistent with HIPAA’s definition of “person,” and as defined in this regulation, an “intermediary” may include entities as well as natural persons. The requirements for intermediaries were proposed to remain unchanged but to be redesignated from § 2.13(d) (Lists of disclosures) to new § 2.24 (Requirements for intermediaries).

Comment

Approximately half of the commenters on intermediaries opposed the Department’s proposal to define intermediary and retain consent requirements for disclosures to intermediaries that differ from consent for disclosures to business associates generally. Three-fourths of the HIE/HIN and health IT vendors that commented on this set of proposals opposed them. Several commenters, including a national trade association and a leading authority on the use of health IT, stated that the proposed definition is too vague and confusing.

Response

We appreciate these comments about the lack of clarity in the current understanding and proposed definition of “intermediary.” As we stated in the NPRM, the term “intermediary” is based on the function of the person—receiving records from a part 2 program and disclosing them to other providers as a key element of its role—rather than on a title or category of an organization or business. We agree that the interaction of this term with “program,” “business associate,” and “covered entity” is a source of confusion and believe a modified definition could address this confusion.

Comment

Commenters suggested a range of changes to the proposed definition. These included revising the HIPAA definition of “covered entity” to include examples of the intermediaries and removing the part 2 definition of “intermediary,” excluding the following from the definition of intermediary: business associates, health IT vendors, and health plans; and clarifying what types of HIEs or health IT vendors are included in the definition (because some HIE technology or EHR software does not maintain data or have access to it when exchanging data between systems).

Response

We considered the possibility of removing the part 2 definition of “intermediary” entirely; however, that would leave a gap in privacy protection for records that are disclosed to intermediaries that are not subject to HIPAA requirements. For example, intermediaries may include research institutions and care coordination organizations that are not always subject to HIPAA. We adopt the proposed language of the definition with modification: we exclude programs, covered entities, and business associates, in part because the primary requirement of intermediaries—to provide a list of disclosures upon patient request—is similar to the new accounting of disclosures requirements that the CARES Act applied to part 2 programs and that already applies to covered entities and business associates.

For clarification, we reiterate here that a research institution that is not providing treatment would not be considered an intermediary because it would not have member participants with a treating provider relationship to a patient. A health app that is providing individual patients with access to their records would not be considered an intermediary unless it is also facilitating the exchange of part 2 records from a part 2 program to other treating providers using a general designation in a consent.

We also clarify that member participants of an intermediary refers to health care provider practices or health-related organizations, such as health plans. The member participants of an intermediary may or may not be covered entities. Individual health plan subscribers (*i.e.*, enrollees, members of a health plan) are not considered member participants of an intermediary, although they may access records through an EHR, because they are not providers or health-related organizations. Further, employees of providers or health-related organizations who share access to the same EHR system are not considered member participants of an intermediary because the employer as an entity is considered the participant. However, an HIE/HIN that is providing services to a part 2 program that is not a covered entity would be an intermediary (and the HIE/HIN would also be a QSO).

Comment

An SUD provider recommended modifying the proposed definition of “intermediary” to include “a member of the intermediary named in the consent,” rather than limiting it to members of the

intermediary that have a treating provider relationship with the patient.

Response

Expanding the definition of “intermediary” to include any member participant would open the door to accessing patients’ SUD records without their specific knowledge in advance (because the recipient would be in a general designation within a consent). Although the CARES Act expanded health plans’ and other providers’ access to records for TPO, we do not believe the intention was to remove all restrictions on access by member participants of a research institution, for example. Removing programs, covered entities, and business associates from the definition carves out a significant portion of entities that would otherwise be subject to the intermediary requirements so that it is not necessary to change the definition as suggested by the commenter.

Final Rule

We are adopting the proposed definition of “intermediary,” but with an exclusion for part 2 programs, covered entities, and business associates. We believe excluding business associates, in particular, will encourage HIEs to accept part 2 records and include part 2 programs as participants and reduce burdens on business associates that serve as HIEs.

Investigative Agency

The Department proposed to create a new definition of “investigative agency” to describe those government agencies with responsibilities for investigating and prosecuting part 2 programs and persons holding part 2 records, such that they would be required to comply with subpart E when seeking to use or disclose records against a part 2 program or lawful holder. In conjunction with proposed changes to subpart E pertaining to use and disclosure of records for investigating and prosecuting part 2 programs, the Department proposed to define an “investigative agency” as “[a] state or federal administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding part 2 records.” Such agencies potentially will have available a new limitation on liability under § 2.3 if they unknowingly obtain part 2 records before obtaining a court order for such records, provided they meet certain prerequisites.

Comment

Several commenters recommended that local, territorial, and Tribal investigative agencies be added to the definition of “investigative agency” because they have a role in investigations of part 2 program. These commenters asserted, for instance, that local agencies play a role in investigating or prosecuting part 2 programs or other holders of part 2 records and excluding them from the definition could create an uneven application of the law.

Response

We appreciate the feedback in response to the request for comment on whether other types of agencies should be included in the definition of “investigative agency”, and specifically whether adding agencies that may be smaller or less resourced would present any concerns or unintended consequences. We believe it is useful to include local, Tribal, and territorial agencies in the definition; however, such agencies should be aware that use of the safe harbor also requires reporting to the Secretary of instances when it is applied in an investigation or proceeding against a part 2 program or other holder of records.

Comment

A few commenters recommended narrowing the definition of “investigative agency” by excluding agencies that supervise part 2 programs, to avoid creating uncertainty about whether, in performing their supervisory functions, they are expected to obtain a court order to use or disclose part 2 records of their subordinate programs. For example, a state agency believed that, as proposed, the safe harbor applies whenever an agency has obtained records without a court order—thus the existence of the safe harbor implies that a court order may be required for all types of investigations, even when other part 2 disclosure permissions apply, such as § 2.53 (Management audits, financial audits, and program evaluation). They expressed concern that holders of records may resist legitimate agency requests for records and urge the agency to first seek a court order. One commenter recommended clarifying that existing permissions for agencies to obtain records without a court order still apply. Another commenter pointed out that § 2.12(c)(3)(ii) already allows unlimited communication “[b]etween a part 2 program and an entity that has direct administrative control over the program,” which includes government-

run SUD programs and administering agencies.

Response

We appreciate these concerns and believe that the existing criteria for court orders are sufficient to prevent overuse of the court order process by government agencies. Specifically, §§ 2.66 and 2.67 require a finding by the court that “other ways of obtaining the information are not available.” These include, for example, § 2.12(c) for agencies with direct administrative control and § 2.53 for agencies with oversight roles or that act as third-party payers. We believe that the existing disclosure permissions for government agencies are sufficient to clarify the scope of access to records by supervisory agencies without obtaining a court order and that our explanation will reinforce agencies’ abilities to continue to obtain part 2 records under permissions they have historically used and not burden courts with unnecessary and potentially ineffective applications for court orders. We reiterate here that the existence of the safe harbor provision and the opportunity to seek a court order retroactively do not affect the availability of other part 2 provisions that allow access to records without written consent or a court order.

We believe this discussion will encourage investigative agencies to evaluate how other disclosure permissions may apply to their requests for records when they are in the role of a supervisory agency to a part 2 program.

Comment

One commenter, a state Medicaid fraud unit, recommended that their agency be excluded from the proposed definition of “investigative agency” and that they be able to access records without a court order. In the alternative, they support the proposed safe harbor and related procedures proposed in §§ 2.66 and 2.67.

Response

Agencies with oversight authority may continue to rely on § 2.53 to conduct program evaluations and financial audits without obtaining a court order. Comments regarding the ability of a fraud unit to rely on the proposed safe harbor are addressed below in the discussion of § 2.66.

Final Rule

In the final rule we are adopting the proposed definition of “investigative agency” and further modifying it to add local, Tribal, and territorial agencies.

Lawful Holder

Lawful holders are not formally defined within part 2. In the January 2017 final rule, the Department clarified its use of the term “lawful holder”, stating that a “lawful holder” of patient identifying information is an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as a result of one of the exceptions to the consent requirements in the statute or implementing regulations and, therefore, is bound by 42 CFR part 2.¹⁴⁰

Lawful holders are subject to numerous obligations within the regulation, including the following:

- Prohibited from using records in investigations or proceedings against a patient without consent or a court order, § 2.12(d).
- Adopting policies and procedures to protect records received, § 2.16.
- Providing notice upon redisclosure, § 2.32.
- Having a contract in place to redisclose records for payment and health care operations that binds recipients to comply with part 2 and redisclose only back to the program, § 2.33.
- Reporting to Prescription Drug Monitoring Programs only with patient consent, § 2.36.
- Lawful holder that is a covered entity—may apply HIPAA standards for research disclosures, § 2.52.
- Complying with audit and evaluation disclosure provisions, § 2.53.

In the NPRM the Department proposed three key changes that affect lawful holders:

- Section 2.4—to allow patients to file complaints of part 2 violations against both programs and lawful holders.
- Section 2.12(d)—to expressly state that downstream recipients from a lawful holder continue to be bound by the prohibition on use of a patient’s records in proceedings against the patient, absent written consent or a court order.
- Section 2.33(b)(3) and (c)—to exclude covered entities and business associates from certain requirements for lawful holders who have received records based on consent for payment and health care operations; the requirement is for lawful holders to have a written contract (with required provisions) before redisclosing records to contractors or subcontractors. This section also provides that when records are disclosed for payment or health care

operations activities to a lawful holder that is not a covered entity, business associate, or part 2 program, the recipient may further use or disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent on behalf of such lawful holders.

Overview of Comments

Some commenters provided views on whether to create a regulatory definition of “lawful holder,” and if so, what entities should fall within the definition. A significant majority of those commenters recommended creation of a regulatory definition to help provide clarity about responsibilities of respective types of recipients of part 2 records and none opposed a new regulatory definition. A few organizations did not make a specific recommendation in their comments about a regulatory definition of lawful holder but requested that the Department provide clarification in the final rule. Several commenters offered other views on lawful holders. Additional comments about lawful holders are included in the comments on intermediaries.

Comment

Commenters recommended various definitions of “lawful holder” that exclude covered entities, business associates, family members, or personal representatives.

Response

We appreciate these recommendations. We are not excluding part 2 programs, covered entities, and business associates from the finalized regulatory definition of lawful holder when they receive part 2 records from a part 2 program. However, covered entities and business associates that receive part 2 records based on a TPO consent may redisclose them as permitted by § 2.33(b)(1) and part 2 programs that are not covered entities or business associates, and that receive part 2 records based on a TPO consent, may redisclose the records for TPO as permitted by § 2.33(b)(2). These recipients of part 2 records (part 2 programs, covered entities, and business associates) are not subject to the additional limitations in § 2.33(b)(3) and (c) that apply to other lawful holders who have received records based on consent for payment and health care operations. Family members remain included as lawful holders; however, they are excluded from the requirements

¹⁴⁰ See 82 FR 6052, 6068. See also 81 FR 6988, 6997.

in § 2.16 to have formal policies and procedures to protect records.

Comment

Commenters recommended that the lawful holder provision provide a safe harbor from the imposition of civil or criminal monetary penalties under the HIPAA Breach Notification Rule for the unintentional redisclosure of part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under the HIPAA Privacy Rules TPO permission.

Response

We appreciate the feedback but decline to create a new safe harbor for unintentional violations by lawful holders because we believe the existing penalty tier under the HITECH Act for “did not know” violations is appropriate to address these types of violations.

Comment

An advocacy organization for behavioral health recommended that the Department define mobile health apps that are business associates as “lawful holders” and consider whether other health care interoperability applications or mobile health apps would also fall within the new definition.

Response

We appreciate this feedback on how technology may interact with the part 2 regulations. Because we are excluding business associates from certain requirements that apply to “lawful holders” a mobile health app that is a business associate would also be excluded. However, we do not believe a technology would qualify on its own as a business associate, but rather the owner or developer of the technology that qualifies as a person capable of executing a business associate agreement. To the extent that the owner or developer of a health app, through the use of its technology, becomes a recipient of records in the manner described in the definition of “lawful holder,” it would be a lawful holder subject to the requirements and prohibitions on lawful holders of part 2 records.

Comment

A state agency urged that the rule add lawful holders and intermediaries to § 2.12 to permit them to verbally receive part 2 information and include it in a record without it being considered a part 2 record.

Response

We appreciate this recommendation, but do not believe it is necessary for several reasons. First, we are finalizing the definition of “lawful holder” and the definition of “intermediary” (that excludes covered entities and business associates). Thus, covered entities and business associates will not be subject to requirements for lawful holders or intermediaries. Second, we are finalizing changes to § 2.12(d) that: (a) expressly state that data segmentation and record segregation is not required by part 2 programs, covered entities, and business associates that have received records based on a single consent for all future TPO; and (b) remove language requiring segmentation of part 2 data or segregation of records. As a result of these changes, to the extent a lawful holder or intermediary is a part 2 program, covered entity, or business associate, it is not required to segregate the information, but it is still considered a part 2 record subject to the prohibition against disclosure in proceedings against a patient. Third, the existing rule contains a provision for non-part 2 providers who document verbally shared part 2 information, excluding that information from part 2 status. Thus, only a small set of recipients are still subject to the data segregation requirement, taking into account the combination of changes finalized within this rule.

Comment

One commenter, a medical professionals association for SUD providers, recommended that the definition of “lawful holders” encompass entities with access to individual part 2 records outside the HIPAA/HITECH and part 2 rules, and that the Department should clarify that mobile health apps and “interoperability applications” that are business associates of covered entities would be considered lawful holders.

Response

Rather than refer to specific types of entities, we believe a definition based on the status of the person with respect to how they received subject records is a more workable definition and likely to facilitate common understanding. In this regard, whether a person is a managed care organization or mobile app, if that person received records pursuant to a part 2-compliant consent with an accompanying notice of disclosure, or as a result of a consent exception, the person will be properly considered a lawful holder under this final rule.

Final Rule

The final rule adds a new regulatory definition of “lawful holder” that is based on SAMHSA’s previous explanations and guidance, to read as noted in § 2.11.

Part 2 Program Director

To foster alignment between the HIPAA regulations and the part 2 Rules, the Department proposed to replace the first instance of the term “individual” with the term “natural person” and the other instances of the term “individual” with the term “person” within the definition of “part 2 program director.”

Comment

As noted below, the Department received general support for its proposal to align the definition of person within part 2 with the HIPAA definition of person in 45 CFR 160.103.

Response

We appreciate the comments on the proposed changes.

Final Rule

The final rule adopts the proposed definition of “part 2 program director” without further modification. The Department believes that this change will foster alignment with HIPAA and understanding of HIPAA and the part 2 rules.

Patient

The Department proposed to add language to the existing definition to clarify that when the HIPAA regulations apply to part 2 records, a “patient” is an individual as that term is defined in the HIPAA regulations.

Comment

The Department received general support for further aligning the part 2 definition of patient with the definition of individual within the HIPAA regulations.

Final Rule

The final rule adopts the proposed definition of “patient” without further modification.

Patient Identifying Information

Request for Comment

The Department did not propose changes to the definition of “patient identifying information” but requested comment on all proposed changes to part 2, including the modifications to the de-identification standard in §§ 2.16, 2.52, and 2.54.

Comment

Comments on the proposed de-identification standard are discussed in the sections listed above where de-identification is applied.

Response

In addressing the comments received on the proposed de-identification standard and developing additional modification to better align part 2 with the HIPAA de-identification standard in 45 CFR 164.514(b), we identified additional changes needed to clarify and align terms related to de-identification, including “patient identifying information.” These changes are described below.

Final Rule

We are finalizing a modification to clarify the definition of “patient identifying information” and ensure consistency with the de-identification standard incorporated into this final rule. This change is in response to comments received on the NPRM and to align with the finalization of the de-identification standard in §§ 2.16, 2.52, and 2.54, and is consistent with the Department’s existing interpretation of the term. The final rule retains the part 2 term, “patient identifying information,” rather than replacing it with the HIPAA term, “individually identifiable health information,” because the two regulatory schemes apply to different sets of health information and the CARES Act mandate for alignment did not erase those distinctions.

The first sentence of the definition of “patient identifying information” lists the following identifiers: name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in § 2.11, can be determined with reasonable accuracy either directly or by reference to other information. This identifying information is consistent with the identifiers listed in 45 CFR 164.514(b)(2)(i) of the HIPAA Privacy Rule that must be removed from PHI for it to be considered de-identified and no longer subject to HIPAA protections. As explained in the background section of this rule, the Department clarified in a 2017 final rule that the definition of patient identifying information in part 2 includes the individual identifiers listed in the HIPAA Privacy Rule at 45 CFR 164.514(b)(2)(i) for those identifiers that are not already listed in the part 2 definition, and in preamble listed those identifiers.¹⁴¹

However, the second sentence of the definition of “patient identifying information” in the part 2 rule currently in effect allows retention of “a number assigned to a patient by a part 2 program, for internal use only by the part 2 program, if that number does not consist of or contain numbers (such as a social security, or driver’s license number) that could be used to identify a patient with reasonable accuracy from sources external to the part 2 program.” This exclusion from the definition for a number that could be a part 2 program’s equivalent of a medical record number conflicts with one of the identifiers that must be removed under the HIPAA de-identification standard (and that is listed in the 2017 Part 2 Final Rule), namely, “[a]ny other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section[.]” Paragraph (c) of § 164.514 allows a covered entity to assign a code or other record identifier that can be used to re-identify the PHI, but it must be kept secure and not used for any other purpose. The allowable code referred to in paragraph (c) is different from the number assigned to a patient by a part 2 program, which is more likely to be a provider’s internal record identifier that may be ubiquitous throughout a patient’s medical record. Thus, we believe a clarification of the current rule is needed that removes the last sentence of the definition of patient identifying information.

The final rule adopts a modified definition of “patient identifying information” to align more closely with the HIPAA standard in 45 CFR 164.514.

Payment

The Department proposed to adopt the same definition of this term as in the HIPAA regulations. This proposal would implement 42 U.S.C. 290dd–2(k), added by section 3221(d) of the CARES Act, requiring the term “payment” in this part be given the same meaning of the term for the purposes of the HIPAA regulations.

Comment

The Department received general support for aligning the part 2 definition of payment with the HIPAA definition.

Response

We appreciate the comments on adopting the HIPAA definition of “payment” and confirm that the intent is to uniformly apply the term “payment” in both this regulation and the HIPAA context.

Final Rule

The final rule adopts the proposed definition of “payment” without further modification.

Person

The term “person” is defined within part 2 as “an individual, partnership, corporation, federal, state or local government agency, or any other legal entity, (also referred to as ‘individual or entity’).” The part 2 regulation uses the term “individual” in reference to someone who is not the patient and therefore not the subject of a part 2 record. In contrast, the HIPAA regulations at 45 CFR 160.103 define the term “individual” to refer to the subject of PHI, and “person” to refer to “a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.” Thus, the HIPAA definition includes both natural persons and corporate entities.

To further the alignment of part 2 and the HIPAA regulations and provide clarity for part 2 programs and entities that must comply with both sets of requirements, the Department proposed to replace the part 2 definition of “person” with the HIPAA definition in 45 CFR 160.103. As an extension of this clarification, the Department further proposed to replace the term “individual” with “patient” when the regulation refers to someone who is the subject of part 2 records, to use the term “person” when it refers to someone who is not the subject of the records at issue, and to modify the definition of “patient” in part 2 to include an “individual” as that term is used in the HIPAA regulations. The Department stated that this combination of modifications would promote the understanding of both part 2 and the HIPAA regulations and requested comment on whether this or other approaches would provide more clarity.

Comment

Commenters generally supported this proposed change as providing clarity and helping to align with HIPAA. One commenter, a county SUD provider, suggested that referring to “person” is helpful for clarity and also emphasizes patient autonomy and whole person care. Another commenter supported the efforts throughout the rulemaking to streamline language by replacing the phrase “individual or entity” with the word “person,” but questioned use of this term in § 2.51 (Medical emergencies).

¹⁴¹ See 82 FR 6052, 6064.

Response

We appreciate the comments. We confirm here that within this rule “person” refers to both a natural person and an entity, which may include a government agency, a health care provider, or another type of organization. Thus, the term “person” in the new safe harbor at § 2.3 applies to an investigative agency as well as a natural person who is acting under a grant of authority from an investigative agency. The comment about disclosures for medical emergencies is discussed further in § 2.51 (Medical emergencies).

Final Rule

The final rule adopts the proposed definition of “person” without further modification.

Personal Representative

The Department did not propose a regulatory definition of “personal representative” for this rule but requested comment on whether to do so and apply it to § 2.15 which addresses surrogate decision making for patients who are deceased or lack capacity to make decisions about their health care. Under the existing § 2.15(a)(1) provision, consent for disclosures of records may be given by the guardian or other individual authorized under state law to act on behalf of a patient who has been adjudicated as lacking capacity, for any reason other than insufficient age, to manage their own affairs. In circumstances without adjudication, under § 2.15(a)(2) the part 2 program director may exercise the right of the patient to consent to disclosure for the sole purpose of obtaining payment for services from a third-party payer for an adult patient who for any period suffers from a medical condition that prevents knowing or effective action on their own behalf.

The existing rule, at § 2.15(b)(2), requires a written consent by an executor, administrator, or other personal representative appointed under applicable state law for disclosures for a deceased patient’s record. If there is no legally appointed personal representative, the consent may be given by the patient’s spouse or, if none, by any responsible member of the patient’s family. However, part 2 does not define any of the terms for the persons who can provide the consent, including “personal representative.”

Comment

Several commenters, including state agencies and health technology vendors, suggested that the Department provide that personal representatives can give consent to use and disclose part 2

records on behalf of an incapacitated patient. One of the state agencies commented that such a grant of authority to personal representatives would help ensure care coordination. All agreed that the Department should define “personal representative” and a few of these commenters commented that the Department should define it consistent with HIPAA. Specifically, a few of these commenters described facilities being faced with requests for records by many individuals of varying relationships to patients. They asserted that the NPRM leaves room for interpretation about who has authority, making it difficult to ensure patient privacy consistent with HIPAA.

Response

We acknowledge and agree with the commenters who provided views on this topic. HIPAA does not include “personal representative” in its definitions section but provides a clear standard in 45 CFR 164.502(g)(2), where it describes the responsibilities of a personal representative as having “authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care.” Section 164.502(g) provides when, and to what extent, a personal representative must be treated as the individual for purposes of the HIPAA Privacy Rule. Section 164.502(g)(2) requires a covered entity to treat a person with legal authority to act on behalf of an adult or emancipated minor in making decisions related to health care as the individual’s personal representative with respect to PHI relevant to such personal representation. Adopting a definition in the final rule will clarify who qualifies as a personal representative for decisions about uses and disclosures for adults who lack the capacity to make decisions about consenting to uses or disclosures of their SUD records and provide needed consistency between part 2 and the HIPAA Privacy Rule. Defining the term “personal representative” consistent with the HIPAA standard furthers the alignment of part 2 and HIPAA in accordance with the CARES Act and will also assist with treatment and care coordination. We considered but decline to adopt 45 CFR 164.502(g) in its entirety because several paragraphs conflict with part 2, such as consent by minors, and we believe it is important to maintain those provisions of part 2 that are more protective of patient privacy.

Final Rule

We are finalizing in § 2.11 a new regulatory definition of “personal

representative” that mirrors language in the HIPAA Privacy Rule at 45 CFR 164.502(g).

Program

Within the definition of “program,” the Department proposed to replace the term “individual or entity” with the term “person” as is used in the HIPAA regulations and make no other changes. Part 2 defines program as: (1) An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or (3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

Comment

The Department received several comments on the existing definition of “program,” including several elements for which no changes were proposed. Some providers commented that they continue to be confused as to the meaning of “holds itself out.” Commenters also requested clarity as to whether they or their facility’s “primary function” was the provision of SUD treatment. Commenters requested more objective definitions of these terms or use of another approach to defining a program, such as HHS creating a central registry of part 2 programs similar to that developed by the Health Resources and Services Administration for health centers or the 340B Drug Pricing Program. Lacking such clarity, commenters asserted that it may be difficult for providers to distinguish between claims that are subject to part 2 consent or other provisions from those that are not. Commenters also asked whether a program or provider holds themselves out based on their advertising SUD services or based on their being known to provide, refer, or bill for SUD treatment. One commenter believed that general medical facilities are exempt from the definition of part 2 programs yet in practice, such facilities may offer SUD treatment and this may be widely known in the community. The commenter urged the Department to provide additional clarity is needed on how part 2 applies to general medical facilities or practices given current emphasis on behavioral health integration and care coordination for

patients. Another commenter noted that facilities making it known that they offer SUD treatment can help to reduce stigma and discrimination and encourage patients to seek needed care.

A medical professionals' association asserted that EHRs are not designed to treat some units or locations within a facility, such as emergency departments, differently than others. The commenter urged the Department to define part 2 "program" as being limited to licensed SUD providers to help provide needed clarity. Other commenters suggested that providers may offer medications for opioid use disorder (MOUD) (also known as medication assisted treatment (MAT))¹⁴² but do not specifically hold themselves out as being part 2 programs. Commenters urged the Department to clarify that facilities or providers providing MOUD do not become part 2 programs unless doing so is their primary function.

Response

We did not propose changes to the long-standing definition of a part 2 "program" in 42 CFR part 2, and thus the final rule is limited to interpreting the definition rather than revising it. Whether a provider holds itself out as providing SUD treatment or as a practice with the primary function of providing SUD treatment within a general medical facility setting is a fact-specific inquiry that may depend on how a particular program operates and describes or publicizes its services. That said, the Department acknowledges comments about providers' challenges in applying the definition of part 2 "program" in integrated care settings or using EHRs and other technologies to support coordinated, integrated care. The Department has provided guidance on this issue in the past.¹⁴³ After this rule is final, the Department may update or provide additional guidance to help further clarify the definition of program. The Department has historically noted that most SUD treatment programs are federally assisted and therefore that prong of part 2 typically applies. In 2017, the Department largely reiterated its proposed interpretations of "holds itself out" and "primary function,"¹⁴⁴

and more recently developed guidance on the applicability of part 2.¹⁴⁵

Comment

Another commenter asked that the Department specifically carve out from part 2 IHS and Tribal facilities that provide MOUD incident to their provision of general medical care.

Response

We appreciate the comment; however, this change is beyond the scope of this rulemaking. The Department conducted a Tribal consultation about the CARES Act changes to this rule in March 2022¹⁴⁶ and will continue to provide support to Tribal entities and collaborate with IHS in implementing the final rule. The Department also notes that some facilities and providers, even if they do not meet the definition of program, still may be required by state regulations to comply with part 2 requirements.¹⁴⁷

Final Rule

The final rule adopts the proposed definition of "program" without further modification.

Public Health Authority

The Department proposed to adopt the same meaning for this term as in the HIPAA Privacy Rule at 45 CFR 164.501. This proposal would implement subsection (k) of 42 U.S.C. 290dd-2, added by section 3221(d) of the CARES Act, requiring the term in this part be given the same meaning of the term for the purposes of the HIPAA regulations.

Comment

The Department received a few specific supportive comments, including from several state agencies, that the addition of the proposed definition would facilitate public health authorities' provision of comprehensive health and health care information to the public, and would help clarify the

provision of comprehensive data and information to public health authorities for critical public health needs.

Response

We appreciate the comments.

Final Rule

The final rule adopts the proposed definition of "public health authority" without further modification.

Qualified Service Organization

The Department proposed to modify the definition of "qualified service organization" by adding HIPAA business associates to the regulatory text to clarify that they are QSOs in circumstances when part 2 records also meet the definition of PHI (*i.e.*, when a part 2 program is also a covered entity). The Department stated that this proposal would facilitate the implementation of the CARES Act with respect to disclosures to QSOs. The HIPAA regulations generally permit disclosures from a covered entity to a person who meets the definition of a business associate (*i.e.*, a person who works on behalf of or provides services to the covered entity)¹⁴⁸ without an individual's authorization, when based on a business associate agreement that incorporates certain protections.¹⁴⁹ Similarly, the use and disclosure restrictions of this part do not apply to the communications between a part 2 program and QSO when the information is needed by the QSO to provide services to the part 2 program. This definition is proposed in conjunction with a proposal to modify § 2.12 (Applicability), to clarify that QSOs also use part 2 records received from programs to work "on behalf of" the program.

The Department also proposed a wording change to replace the phrase "individual or entity" with the term "person" as proposed to comport with the HIPAA meaning of the term.

Comment

Several organizations commented on QSOs. A behavioral health advocacy organization supported the proposed change because consent requirements would not apply to information exchanges between part 2 programs and business associates when they are providing "service work" on behalf of the part 2 program and this expansion would encourage data sharing for part 2 programs. A state health data agency recommended eliminating the QSO

¹⁴² This rule follows the convention adopted by SAMHSA of referring to MOUD rather than MAT. See 87 FR 77330, 77338 (Dec. 16, 2022).

¹⁴³ See Substance Abuse and Mental Health Servs. Admin., "Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?" (May 1, 2018), <https://www.hhs.gov/guidance/document/does-part-2-apply-me>.

¹⁴⁴ See discussion at 82 FR 6052, 6066.

¹⁴⁵ See "Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?," *supra* note 143.

¹⁴⁶ See U.S. Dep't of Health and Human Servs., Off. for Civil Rights and the Substance Abuse and Mental Health Servs. Admin., "Follow up Report on the 42 CFR part 2 Tribal Consultation Recommendations" (June 2023), <https://www.samhsa.gov/sites/default/files/follow-up-report-42-cfr-part-2-tribal-consultation-recommendations-june-2023.pdf>.

¹⁴⁷ See California Health & Human Servs. Agency, Ctr. for Data Insights and Innovation, "State Health Information Guidance, 1.2, Sharing Behavioral Health Information in California" (Apr. 2023), <https://www.cdii.ca.gov/wp-content/uploads/2023/04/State-Health-Information-Guidance-1.2-2023.pdf>; see also "TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations," *supra* note 122.

¹⁴⁸ See 45 CFR 160.103 (definition of "Business associate").

¹⁴⁹ See, *e.g.*, 45 CFR 164.504(e).

definition in favor of business associate. The commenter believed that if § 2.3(c) applies the various sanctions of HIPAA to part 2 programs regardless of whether the program is a HIPAA covered entity or business associate, the need to retain QSOs for part 2 programs that are not covered entities seems to be eliminated. A health system commenter has found the existing definition of QSO to be broad, and said that it is difficult to know which recipients are receiving part 2 records. This commenter would support the proposed definition if it meant that compliance with a business associate agreement would meet the part 2 requirements for a QSO agreement (QSOA).

Response

The Department is maintaining a distinct definition in part 2 for QSOs. The revised definition clarifies the obligations of a business associate that has records created by a covered entity that is a part 2 program (which is subject to all part 2 requirements) and a business associate that has records from a covered entity that is only a recipient of part 2 records (and subject to the new redisclosure permission as allowed under the HIPAA Privacy Rule). While QSOs supporting part 2 programs in such activities as data processing and other professional services are analogous to the activities of business associates supporting covered entities, QSOs have a distinct function within part 2. For these reasons, QSOA under part 2 should be understood as distinct from business associate agreements required by HIPAA.

Comment

Another state commenter suggested that QSOs should be included in the breach notification requirements that are being newly applied to part 2 programs.

Response

We considered finalizing a requirement for QSOs to comply with the new breach reporting requirements in § 2.16 in the same manner as they apply to business associates under HIPAA. We believe subjecting QSOs to this requirement would have underscored the status of QSOs as similar to business associates; however, we are not making this change because the CARES Act provides that breach notification should apply to part 2 programs in the same manner as it does to covered entities and does not mention breach notification requirements with respect to QSOs or business associates. Regardless, part 2 programs are likely to address breach

notifications in contractual provisions within a QSOA, so QSOs need to be aware of breach notification.

Comment

A few HIN/HIEs requested that the definition of QSO be modified to expressly include subcontractors of QSOs. The commenters further requested that the Department withdraw prior regulatory guidance regarding “contract agents,” because it has been interpreted by some as requiring a Federal agency-level relationship between the QSO and the QSO’s subcontractor to permit the QSO to engage with a subcontractor.

Response

The Department declines to withdraw previous guidance concerning contract agents or subcontractors, which it still views as relevant. In its 2010 HIE guidance, the Department stated that “[a]n HIO may disclose the Part 2 information to a contract agent of the HIO, if it needs to do so to provide the services described in the QSOA, and as long as the agent only discloses the information back to the HIO or the Part 2 program from which the information originated.”¹⁵⁰ In 2017 the Department noted that “[w]e have previously clarified in responses to particular questions that contracted agents of individuals and/or entities may be treated as the individual/entity.”¹⁵¹ In the 2018 final rule, the Department stated that “SAMHSA guidance indicates that a QSOA does not permit a QSO to re-disclose information to a third party unless that third party is a contract agent of the QSO, helping them provide services described in the QSOA, and only as long as the agent only further discloses the information back to the QSO or to the part 2 program from which it came.”¹⁵²

The Department, in the 2020 Part 2 Final Rule, noted that activities of QSOs “would overlap with those articulated in § 2.33(b) related to information disclosures to a lawful holder’s contractors, subcontractors, and legal representatives for the purposes of payment and/or health care operations.”¹⁵³ This guidance continues to be relevant to the roles of QSOs and their subcontractors or agents.

¹⁵⁰ Substance Abuse and Mental Health Servs. Admin., “Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE),” at 8, <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>.

¹⁵¹ 82 FR 6052, 6056.

¹⁵² 83 FR 239, 246.

¹⁵³ 85 FR 42986, 43009.

Comment

According to one county government, the addition of business associates to the definition of a “qualified service organization” is helpful for the county health system’s ability to serve patients in need of SUD treatment. As a large health system and provider of behavioral health services, this county relies on business associates to operate its programs. A clearer definition of QSOs will allow the county and its part 2 programs to expand services using business associates to provide much needed assistance with claims, data and analytics, and quality assurance, the commenter said.

Response

The Department appreciates the comments on its proposed change.

Comment

An advocacy organization urged HHS to clarify that a business associate must still meet all aspects of the QSO definition, including entering into a QSOA. It also suggested that HHS should consider creating and publishing an official version of a joint QSOA and business associate agreement and that HHS should also work to improve major technology vendors’ understanding of part 2, so that part 2 programs and their patients can benefit from services like email, cloud-based storage, and telehealth platforms, while maintaining confidentiality safeguards. Another commenter said the Department should provide guidance on how terms such as intermediaries, business associates, qualified service organizations, and lawful holders interact and differ.

Response

The Department appreciates these comments and will consider what additional guidance may be helpful after this rule is finalized. The Department explains throughout this rule that the roles and functions of lawful holders, business associates, QSOs, and intermediaries but may provide additional, concise guidance in the future. As highlighted in its guidance entitled “Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?” such inquiries are fact-specific depending on an organization’s or provider’s role in SUD treatment and the records it shares or receives.¹⁵⁴

Final Rule

The final rule adopts the proposed definition of QSO to expressly include

¹⁵⁴ See “Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?” *supra* note 143.

business associates as QSOs where the PHI in question also constitutes a part 2 record and further modifies the new paragraph by adding a clarification that the definition of QSO includes business associates where the QSO meets the definition of business associate for a covered entity that is also a part 2 program. Finalizing the changes to expressly include business associates as QSOs responds to comments received on the NPRM and those from others on previous part 2 rulemakings (such as during SAMHSA's 2014 Listening Session)¹⁵⁵ noting that the role of QSOs is analogous to business associates such that aligning terminology makes sense given the purpose of section 3221 of the CARES Act to enhance harmonization of HIPAA and part 2. As noted in the NPRM, the Department also believes finalizing this proposal facilitates the implementation of the CARES Act with respect to disclosures to QSOs.

Records

The definition of "records" specifies the scope of information that part 2 protects. The Department proposed to insert a clause to expressly include patient identifying information within the definition of records and to remove, as unnecessary, the last sentence that expressly included paper and electronic records.

Comment

Several organizations commented on the definition of "records." Several commenters on the definition of "record" requested that the final rule expressly state that records received from a part 2 program under a consent for TPO no longer retain their characteristic as part 2 records. These commenters provided their views of the difficulties associated with tracking the provenance of a particular data element once it has been added to a record. One comment suggested that the recipient should be able to redisclose the data for TPO even if the provenance could not be tracked.

Response

We appreciate the comments but decline to add a statement that records received under a consent for TPO are no longer part 2 records. Instead, in response to other comments we are finalizing an express statement in § 2.12(d) that segregation of records received by a part 2 program, covered entity, or business associate under a

consent for TPO is not required. We believe it is necessary for the records received to retain their characteristic as part 2 records to ensure that recipients comply with the continuing prohibition on use and disclosure of the records in investigations or proceedings against the patient, absent written consent or a court order. We agree with the comment that a recipient that is a part 2 program, covered entity, or business associate should be able to redisclose the data for TPO as permitted by HIPAA and believe that the suite of modifications in the final rule accomplishes that end.

Comment

According to one commenter, the definitions of "record," "program," and "patient identifying information" and how they are applied are inconsistent, cross-referential, and confusing. This commenter urged the Department to simplify and clarify these terms, perhaps by adopting a single term as used in HIPAA (e.g., "protected health information") to uniformly apply throughout the regulation.

Response

We appreciate this comment and are finalizing a number of changes to improve consistency and clarity throughout the rule; however, we are also mindful that many definitions have a special meaning within this part and the primary aim of this rulemaking is to implement the CARES Act amendments to 42 U.S.C. 290dd–2. We are incorporating the term "patient identifying information" into the definition of record, in part to align with the HIPAA definition of PHI which includes demographic information. Thus, with this modification the definition includes both information that could identify a patient as having or having had an SUD, but also information that identifies the patient.

Comment

An individual commenter recommended that the Department retain the last sentence of the definition because it is helpful to indicate that part 2 may apply to paper and electronic records and removing it might suggest to programs that the regulation no longer applies to paper records.

Response

In the five decades since the promulgation of the part 2 regulation, health IT has become widely adopted and it is evident that records include both paper and electronic formats. The Department does not intend to change the meaning or understanding of records

with this proposed modification, but only to streamline the description.

Final Rule

We are adopting the proposed definition of "records" without further modification.

SUD Counseling Notes

In the NPRM, we requested input about whether to create a new definition similar to psychotherapy notes within HIPAA that is specific to the notes of SUD counseling sessions by a part 2 program professional. Such notes would be part 2 records, but could not be disclosed based on a general consent for TPO. They could only be disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information. We requested comments on the benefits and burdens of creating such additional privacy protection for SUD counseling notes that are maintained primarily for use by the originator of the notes, similar to psychotherapy notes as defined in the HIPAA Privacy Rule. We provided potential language for "SUD counseling notes", defining it as notes recorded (in any medium) by a part 2 program provider who is an SUD or mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the patient's record. "SUD counseling notes" excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.¹⁵⁶

Comment

Many commenters somewhat or strongly supported the Department's proposal to include a definition of "SUD counseling notes." We are finalizing the proposed definition and discuss comments specifically regarding the proposed definition below and other comments relating to consent and disclosure of SUD counseling notes within § 2.31.

Comments Supporting a Proposed SUD Counseling Notes Definition

An SUD recovery organization supported the potential definition. An association of medical professionals also supported establishing a definition of

¹⁵⁵ See "Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?" *supra* note 143; see also, Confidentiality of Alcohol and Drug Abuse Patient Records, Notice of Public Listening Session, 79 FR 26929 (May 12, 2014).

¹⁵⁶ 87 FR 74216, 74230.

“SUD counseling notes” that effectively copies the definition of “psychotherapy notes” under the HIPAA Privacy Rule. A state health department supported an “SUD counseling notes” definition in § 2.11 because this would permit disclosure without patient consent for the purpose of oversight of the originator of the SUD counseling notes to ensure patient safety. Another state agency urged that SUD counseling session notes be treated similarly to psychotherapy notes as now addressed in HIPAA (*i.e.*, SUD counseling notes be given protections equal to psychotherapy notes). A provider supported the addition of a definition of “SUD counseling notes” as written to incorporate the same protections as described in the HIPAA regulations for psychotherapy notes. The provider believed that any perceived burdens to creating a separate definition of SUD counseling notes are outweighed by the benefits of the additional protections by requiring separate authorization for release of the SUD counseling notes. A county agency recommended that we add this protection in alignment with the psychotherapy notes restriction under HIPAA and further suggests that the protection extend to all clinical notes in addition to the notes of SUD counselors. The commenter further recommended that the definition of “counseling notes” include assessment forms. This added protection would safeguard against use of SUD counseling notes in pending legal cases and pending dependency court (child custody) cases.

A hospital commenter supported providing a corresponding protection in part 2 for certain notes for SUD patients, like psychotherapy notes have under HIPAA, but did not support the use of a new term that would differentiate SUD counseling notes from psychotherapy notes. Instead, the hospital recommended using psychotherapy notes or SUD psychotherapy notes for consistency. The commenter also suggested further discussion of the use of the term “psychotherapy notes” in the regulations, since the term continues to generate confusion. The commenter stated that the terms “counseling notes” and “psychotherapy notes” have a different meaning in routine clinical practice and are used frequently, but do not seem to meet the definition in the NPRM.

Response

We appreciate comments concerning our proposed definition of “SUD counseling notes” and respond as follows. As discussed in the NPRM, the intent of the potential definition we

described was to align with HIPAA provisions regarding psychotherapy notes, and we discuss psychotherapy notes further in § 2.31 below.¹⁵⁷ We believe the final definition of “SUD counseling notes” will ease compliance burdens for part 2 programs because the definition almost exactly matches the definition of “psychotherapy notes” under the HIPAA Privacy Rule except for the references to SUD professionals and SUD notes.

As we explained in the 2000 final HIPAA Privacy Rule, psychotherapy notes “are the personal notes of the therapist, intended to help him or her recall the therapy discussion and are of little or no use to others not involved in the therapy.”¹⁵⁸ While the commenter above did not define what it meant by assessment forms, consistent with HIPAA our final definition of “SUD counseling notes” expressly excludes “medication prescription and monitoring, counseling session start and stop times, modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.”

Comment

Several SUD recovery organizations supported a “SUD counseling notes” definition because these notes often contain highly sensitive information that supports therapy. Limiting access to these notes is critical to protect the therapeutic alliance due to the unique risks that patients face due to the highly sensitive information in these notes. An SUD recovery association and SUD provider commented that the Department should protect counseling notes using a new definition similar to psychotherapy notes, require specific consent, and not allow such consent to be combined with consent to disclose any other type of health information. According to these two commenters the patient’s prognosis should be considered a counseling note because it could bias staff toward the patient’s situation; it is subjective and the large turnover of counseling staff results in greater reliance on existing reports. An individual commenter also said that they supported the Department’s version of SUD counseling notes, but

expressed concern about excluding prognosis from SUD counseling notes; they too believed that prognosis is too subjective and its exclusion from the definition could result in bias or prejudice. Given the large turnover of counseling staff and the use of fairly junior clinicians to provide service, prognosis should be considered a counseling note. A few SUD treatment professionals associations also said that counseling notes should be so protected using a new definition similar to psychotherapy notes.

Response

We appreciate comments from SUD recovery organizations and others about our proposed changes. The final definition of “SUD counseling notes” expressly excludes “medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.” Thus, prognosis information is excluded from “SUD counseling notes” under the definition adopted in this final rule. Information critical to the patients’ diagnosis and treatment such as prognosis and test results, should be within the patient’s part 2 record or medical record such that it may be available for such activities as treatment consultation, medication management, care coordination, and billing.¹⁵⁹

Neither HIPAA nor part 2 provides a right of access to psychotherapy notes or SUD counseling notes, but for different reasons. Under HIPAA, although psychotherapy notes are part of the designated record set (because the clinician may use them to make decisions about the individual), they are specifically excluded from the right of access in 45 CFR 164.524. Under part 2, there is no general right of access for part 2 records, and thus there is no right of access for SUD counseling notes, which are a narrow subset of part 2 records. However, under both HIPAA and part 2, clinicians may exercise their discretion and voluntarily provide patients with access to psychotherapy notes and/or SUD counseling notes or a portion of such notes.

¹⁵⁷ See, e.g., 45 CFR 164.501; 45 CFR 164.508; U.S. Dep’t of Health and Human Servs., “Does HIPAA provide extra protections for mental health information compared with other health information?” (Sept. 12, 2017), <https://www.hhs.gov/hipaa/for-professionals/faq/2088/does-hipaa-provide-extra-protections-mental-health-information-compared-other-health.html>; 65 FR 82461, 82497, 82514 (Dec. 28, 2000).

¹⁵⁸ 65 FR 82461, 82623.

¹⁵⁹ See U.S. Dep’t of Health and Human Servs., “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524” (Oct. 20, 2022), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>; 45 CFR 164.501 (definition of “Designated record set”).

Comment

A local government agency supported explicitly defining “SUD counseling notes” as discussed in the NPRM. The commenter said we should clearly define how and where SUD counseling notes must be treated differently from other part 2 records and the HIPAA designated record set. Such clarification will assist dually regulated entities’ efforts to comply with the HIPAA Privacy Rule and Information Blocking requirements.¹⁶⁰ The commenter proposed redefining “HIPAA psychotherapy notes” to include all part 2-defined SUD counseling notes by reference. Such a straightforward alignment would minimize burden and maximize ease of compliance.

Response

We appreciate comments concerning the definition of “SUD counseling notes” including the suggestion to redefine HIPAA “psychotherapy notes” at 45 CFR 164.501 to include SUD counseling notes. However, changes to the HIPAA definitions are outside the scope of this rulemaking.

Comment

A health insurer supported a separate definition of “SUD counseling notes” that makes clear the distinction between these types of notes, other notes, and part 2 records. SUD counseling notes are distinct from other notes, such as psychotherapy and analysis notes, according to this commenter. Most treatment for SUDs is done through individual and group counseling to address specific goals of a treatment plan, the commenter said, so excluding all notes would in effect exclude the disclosure of SUD information, unless there is differentiation between these notes. Even though the commenter recognizes the definitions would overlap in several aspects—such as for consent requirements—it welcomed the overlap, as there would be an additional administrative burden around creating a separate consent for SUD counseling notes if requirements differed within the definition.

Response

We appreciate this comment on our proposed changes. The commenter correctly apprehends that the provisions for SUD counseling notes require that they be separated from the rest of the part 2 and/or medical record to be recognized as “SUD counseling notes”

and afforded additional privacy protection. We agree that the definition of “SUD counseling notes” in this final rule will support patient participation in individual and group SUD counseling. SAMHSA has noted elsewhere the importance of privacy and confidentiality in both individual and group counseling settings.¹⁶¹

Comments Opposing a New SUD Counseling Notes Definition or Requesting Clarification

Comment

A county government asked that HHS make SUD records a specific category of PHI under HIPAA in a way similar to psychotherapy notes. It is inequitable, said the commenter, that patients have more confidentiality of their records when receiving SUD services from a part 2 program versus a primary care provider that is not a part 2 program. A state agency said that the proposed definition of “SUD counseling notes” and the existing definition of “psychotherapy notes” in 45 CFR 164.501 do not accurately capture the intent of the right of access exclusion. The agency suggested using headings of “SUD process notes” and “psychotherapy process notes” to clarify that these are non-clinical notes and avoid creating confusion for patients in understanding what they are in fact requesting to exclude.

Response

We appreciate suggestions concerning changes or clarifications to provisions concerning the definition of HIPAA “psychotherapy notes” at 45 CFR 164.501. However, changes to the HIPAA definitions are outside the scope of our part 2 rulemaking. With respect to SUD counseling notes, we clarify that the exclusion of psychotherapy notes from the right of access in the HIPAA Privacy Rule does not have a parallel in part 2 because part 2 does not contain a right of access. We do not believe that renaming these notes as process notes would promote understanding of their essential nature—that they are separately maintained and intended primarily for use by the direct treating clinician with few exceptions. Further, we do not categorize SUD counseling notes or psychotherapy notes as either

clinical or non-clinical. We expect that they contain a mix of information useful to the clinician but not necessary for routine uses or disclosures for TPO.

Comment

A few HIE associations questioned the definition discussed in the NPRM stating that psychotherapy notes rarely exist as they are not considered in the HIPAA designated record set; therefore, such psychotherapy notes are not accessible under the patient right of access or available in the patient portal. These commenters and others, as discussed below in § 2.31, expressed concern about the need to keep such records compartmentalized or distinct from other part 2 records and associated burdens for data sharing, health IT, and other activities.

Response

As the Department explained in guidance, “[d]esignated record sets include medical records, billing records, payment and claims records, health plan enrollment records, case management records, as well as other records used, in whole or in part, by or for a covered entity to make decisions about individuals.”¹⁶² Psychotherapy notes are used by the treating clinician to make decisions about individuals, and thus are part of the designated record set, but, they are expressly excluded from the individual right of access to PHI.¹⁶³ However, the HIPAA Privacy Rule permits a treating provider to voluntarily grant an individual access to such notes.¹⁶⁴ Similarly, § 2.23 permits, but does not require, part 2 programs to provide a patient with access to part 2 records (including SUD counseling notes as finalized here), based on the patient’s consent. As explained above, changes to the HIPAA Privacy Rule definition of “psychotherapy notes” are beyond the scope of this rulemaking.

Comment

A health care provider asserted that it is not necessary to create a separate term and definition of SUD counseling notes because the HIPAA term “psychotherapy notes” meets these

¹⁶² U.S. Dep’t of Health and Human Servs., “What personal health information do individuals have a right under HIPAA to access from their health care providers and health plans?” (June 24, 2016), <https://www.hhs.gov/hipaa/for-professionals/faq/2042/what-personal-health-information-do-individuals/index.html>.

¹⁶³ See “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524,” *supra* note 159.

¹⁶⁴ The HIPAA Privacy Rule expressly permits disclosures of PHI to the individual who is the subject of the PHI. See 45 CFR 164.502(a)(1)(i).

¹⁶⁰ See The Off. of the Nat’l Coordinator for Health Info. Tech. (ONC), “Information Blocking”, <https://www.healthit.gov/topic/information-blocking>.

¹⁶¹ See Substance Abuse and Mental Health Servs. Admin., “TIP 41: Substance Abuse Treatment: Group Therapy” (2015), <https://store.samhsa.gov/product/TIP-41-Substance-Abuse-Treatment-Group-Therapy/SMA15-3991>; Substance Abuse and Mental Health Servs. Admin., “TIP 63: Medications for Opioid Use Disorder—Full Document” (2021), <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Documents/PEP21-02-01-002>.

needs. The commenter supported applying the HIPAA standard to psychotherapy notes created within a part 2 program.

Response

We appreciate this comment. As noted in the NPRM, we believe that it is important to include within part 2 a definition of “SUD counseling notes” specific to the notes of SUD counseling sessions by a part 2 program professional. SUD counseling notes under this final rule are part 2 records but cannot be disclosed based on a general consent for TPO. If this rule failed to include a definition of SUD counseling notes HIPAA’s psychotherapy notes provisions and definitions in 45 CFR 164.501 and 164.508 would not apply to part 2 programs that are not covered entities and SUD counseling notes could be disclosed under a general TPO consent, which would undermine the utility of these notes being maintained separately from the designated record set by some SUD providers.

Comment

A county health department stated that SUD counseling notes are different from psychotherapy notes, which often focus on more intimate and deeper clinical considerations, while SUD counseling notes often include more straightforward clinical details that do not require additional privacy protections. This commenter stated that the differences in the nature of such notes is due to differences in the scope of practice of the different workforces of SUD programs and therapists. The commenter also stated that, because most of the services provided by part 2 programs are documented via SUD counseling notes, requiring separate consent for SUD counseling notes would counteract the aim of facilitating greater information exchange without providing a clear benefit. As such, the commenter urged the Department to reject the idea of applying additional privacy protections for SUD counseling notes.

Another county department similarly stated that the nature of SUD counseling notes is fundamentally different from psychotherapy notes, and does not warrant enhanced confidentiality. As described by this commenter, while psychotherapy notes focus on intimate and nuanced clinical considerations, the typical SUD counseling note is far less detailed and more like a standard progress note in a medical record. In addition, SUD counseling notes are usually kept by providers with less education and training than

psychiatrists, who do not have a professional practice of maintaining separate counseling notes primarily for use by the originator of the notes.

A state agency expressed concern that adopting special protections for SUD counseling notes would create additional administrative complexity and compliance challenges for part 2 programs and may have unintended adverse consequences by restricting patient access to, or beneficial disclosures of, a significant segment of their SUD treatment records. The commenter asserted that such a change seemed unlikely to facilitate information exchange for care coordination purposes, and thus would seem to be inconsistent with many of the other proposed amendments.

Response

We acknowledge comments that SUD counseling notes and psychotherapy notes are not precisely equivalent. However, SUD counseling notes, like psychotherapy notes, may also include particularly sensitive details about a patient’s medical conditions and personal history. Such concerns may be especially acute, for instance, with pediatric patients¹⁶⁵ or patients who have or are at risk of conditions such as human immunodeficiency virus (HIV).¹⁶⁶ While these commenters’ anecdotal accounts are helpful to our understanding of the issues, these experiences and comments, do not necessarily apply to the majority of SUD counseling situations in which the clinician’s notes may play an important role in patient treatment and necessitate the additional protections made available in this final rule. More than two-thirds of commenters on this issue expressed support for moving forward with a new definition and heightened protections for SUD counseling notes.

Comment

A health care provider expressed support for an approach that destigmatizes SUD treatment and promotes access to clinically relevant information that is valuable and informative for all TPO purposes. As

¹⁶⁵ See Substance Abuse and Mental Health Servs. Admin., “Treatment Considerations for Youth and Young Adults with Serious Emotional Disturbances and Serious Mental Illnesses and Co-occurring Substance Use” (2021), <https://www.samhsa.gov/resource/ebp/treatment-considerations-youth-young-adults-serious-emotional-disturbances-serious>.

¹⁶⁶ See Substance Abuse and Mental Health Servs. Admin., “Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders” (2020), <https://store.samhsa.gov/product/Prevention-and-Treatment-of-HIV-Among-People-Living-with-Substance-Use-and-or-Mental-Disorders/PEP20-06-03-001>.

such, the provider did not believe that creating additional protections for SUD counseling notes would promote access and exchange of valuable information. An SUD treatment provider association urged the Department to limit disclosures of patient information that are not necessary for the purpose of the disclosure, such as details of trauma history that are not needed for TPO, except by the treating clinician. An insurance association suggested that a new definition of “SUD counseling notes” could be beneficial in some circumstances when heightened privacy is warranted. But a new definition also could impede care coordination because SUD counseling notes may contain clinically relevant information and help inform coordinated treatment plans, according to this commenter, who also asserted that some programs may have difficulty implementing the requirement and be unable to share the remainder of the record for TPO. The commenter urged the Department not to create a separate category for SUD counseling notes but instead to allow SUD providers to determine how to best record these notes. Another insurance association requested that the Department use this rule as an opportunity to: (1) reinforce the existing HIPAA restrictions on sharing psychotherapy notes; and (2) clarify that SUD counseling notes are not psychotherapy notes and maybe used and disclosed for TPO.

Response

We acknowledge these comments and discuss additional related provisions below in § 2.31. We do not believe the final “SUD counseling notes” definition will contribute to stigma or discrimination for SUD patients because it strengthens confidentiality for the most sensitive information shared during treatment and does so in a manner similar to what already exists in the HIPAA regulations. We do not agree that the “SUD counseling notes” definition will impede care coordination because the nature of these notes is that they are intended primarily for use by the direct treating clinician. We agree that the final rule may be an opportunity to provide additional education on existing HIPAA psychotherapy note provisions and will consider what additional guidance may be helpful after this rule is finalized. In addition, we note that a part 2 program’s use of separate SUD counseling notes is voluntary and optional—although a program may adopt a facility-wide policy that either supports or disallows the creation and maintenance of such notes. As noted above, through the

separate definition adopted in this final rule in § 2.11, SUD counseling notes under this final rule are part 2 records but cannot be disclosed based on a TPO consent.

Comment

A medical professionals association expressed concern about potential challenges associated with maintaining SUD counseling notes, noting that the creation of a distinct class of psychotherapy notes in HIPAA provides an illustrative example of the challenge of implementing specific data protections within a medical record: although the “psychotherapy notes” option was added to HIPAA to protect psychotherapist-patient privilege, this option specifically excludes key elements of psychotherapy session notes that are required for routine clinical care as well as for billing purposes (*e.g.*, medication prescription and monitoring, summary of diagnosis, treatment plan). As a result, according to this commenter, if a HIPAA-defined “psychotherapy note” is used, it must always be accompanied by a clinical note that includes the essential elements for routine clinical care and billing.

Response

We acknowledge this comment and appreciate the analogy to HIPAA psychotherapy notes in clinical practice; however, we believe the framework is a valuable option for some clinicians, with the understanding that the notes are intended to be used only by the clinician. Neither the HIPAA Privacy Rule nor this final rule mandate the use within a mental health practice or a part 2 program of “psychotherapy notes” or “SUD counseling notes” as defined within the respective regulations. However, clinicians who choose to keep separate notes for their own use are afforded some additional privacy and the patient’s confidentiality is also protected by additional consent requirements under § 2.31(b) (Consent required: SUD counseling notes).

Comment

A medical professionals association suggested that the Department create a regulatory definition of an “SUD professional” who is qualified to perform treatment and prepare SUD counseling notes.

Response

The definition of “SUD counseling notes” matches the definition of “psychotherapy notes” under the HIPAA Privacy Rule except for the references to SUD professionals and SUD notes. Historically, the Department

has considered licensed providers as “professionals.” We did not propose and therefore are not finalizing a definition of SUD professionals either separately or in relation to SUD counseling notes. The exception to the consent requirement for use in a part 2 program’s training program indicates that an “SUD professional” may be someone who is completing their practical experience to receive a degree or professional certification or license, and, additionally, that such notes may be used in clinical supervision.

Final Rule

The final rule adopts the definition of “SUD counseling notes” as proposed in the NPRM.

Third-Party Payer

The term “third-party payer” refers to an entity with a contractual obligation to pay for a patient’s part 2 services and includes some health plans, which by definition are covered entities under HIPAA. The current regulation, at § 2.12(d)(2), limits disclosures by third-party payers to a shorter list of purposes than the HIPAA Privacy Rule allows for health plans. The Department proposed to exclude covered entities from the definition of “third-party payer” to facilitate implementation of 42 U.S.C. 290dd–2(b)(1)(B), as amended by section 3221(b) of the CARES Act, which enacted a permission for certain recipients of part 2 records to redisclose them according to the HIPAA standards. The result of this proposed change would be that the current part 2 disclosure restrictions continue to apply to a narrower set of entities. The Department believes that this approach would carry out the intent of the CARES Act, while preserving the privacy protections that apply to payers that are not covered entities. The Department also proposed a wording change to replace the phrase “individual or entity” with the term “person” as now proposed to comport with the HIPAA meaning of the term.

Comment

The Department received overwhelmingly supportive comments on the intent to distinguish health plans, which are covered entities, from other third-party payers who would be subject to part 2 (but not HIPAA). The rationales offered for supporting this proposal were that it furthers the implementation of the CARES Act requirement to align part 2 with HIPAA, reduces the need to segment part 2 records, reduces health plan burden, and allows health plans to engage in more activities that improve health care,

such as care coordination and accountable care.

Response

We appreciate the comments.

Comment

Several commenters stated that the definition could be confusing to some readers and requested clarification in the final rule along with additional examples of entities that would remain subject to part 2 as third-party payers. Specifically, a trade association requested that the Department exclude business associates of health insurance providers (*i.e.*, a health plan/payer) from this definition because they are not independent “third-party payers” but rather are acting on behalf of a health insurance provider. A health system requested that the Department ensure that ACOs and population health providers have access to full part 2 information without a beneficiary having to explicitly opt-in to data sharing.

Response

We appreciate the comments and clarify that business associates acting on behalf of health plans are not independent “third-party payers” who would fall within this definition. However, business associates are listed along with covered entities in the new language of § 2.12(d)(2)(i)(C), which expressly states that covered entities and business associates are not required to segregate records or segment part 2 data once received from a part 2 program based on a TPO consent.

Comment

One commenter asserted that the proposed rule did not clearly address the role of third-party payers, including the more active role of these entities in coordinating patient care. This commenter cited, for example, that third-party payers could provide direct care coordination; services such as home health visits as a covered entity; or function solely as a third-party payer, making payment and overseeing quality claims reporting for providers. The commenter cited the Ohio Medicaid Comprehensive Privacy Care or “CPC” alternative payment program as an example where health plans act as managed care organizations that oversee various avenues of payment as well as core coordination in conjunction with providers. This commenter also believed that the definition is intended to ensure that third-party payers that are not HIPAA covered entities are also subject to the same rules as a covered entities with respect to part 2 records

and recommended that HHS clarify the definitions of “covered entity” and “third-party payer” to explain the relationship between these groups and the obligations of each with respect to part 2 information.

Response

We appreciate the commenter’s description of new models of payment and care coordination. However, we believe the commenter misapprehends the intent of the proposed definition, which is finalized in this rule. The intent is to distinguish third-party payers, which are not covered entities, from health plans (which, by definition, are covered entities). If a third-party payer is not a covered entity, then it is not subject to part 2 provisions that apply to covered entities except when (a) specifically identified as being subject to these provisions or (b) in those instances where third-party payers are lawful holders by virtue of having received part 2 records under a written consent or an exception to the consent requirements. For example, some non-profit organizations provide health care reimbursement for individuals and some entities provide payment as part of an insurance policy that does not meet the definition of health plan in HIPAA.

Final Rule

The final rule adopts all proposed modifications to the definition of “third-party payer” in § 2.11, without further modification.

Treating Provider Relationship

The Department proposed to modify the part 2 definition of “treating provider relationship” by replacing the phrase “individual or entity” with “person,” in accordance with the proposed changes to the definition of “person” described above. Additionally, several minor wording changes were proposed for clarity.

Comment

We received no comments on the proposed changes to this definition.

Final Rule

The final rule adopts the proposed changes to the definition of “treating provider relationship” without further modification.

Treatment

The Department proposed to modify the part 2 definition of “treatment” by adopting the HIPAA Privacy Rule definition in 45 CFR 164.501 by reference. This would implement subsection (k) of 42 U.S.C. 290dd–2, added by section 3221(d) of the CARES

Act, requiring that the term be given the same meaning of the term for the purposes of the HIPAA regulations. As discussed in the NPRM, by replacing the existing language, the Department does not intend to change the scope of activities that constitute treatment. In this context, treatment includes the care of a patient suffering from an SUD, a condition which is identified as having been caused by the SUD, or both, to reduce or eliminate the adverse effects upon the patient.

Comment

In addition to the supportive comments discussed above, a state government expressed specific support for the adoption of the HIPAA definition of the term “treatment.”

Response

We appreciate the comments.

Final Rule

The final rule adopts all proposed modifications to the definition of “treatment” in § 2.11, without further modification.

Unsecured Protected Health Information

The Department proposed to adopt the same meaning of this term as used in the HIPAA regulations at 45 CFR 164.402 to mean PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in guidance. This proposal would implement subsection (k) of 42 U.S.C. 290dd–2, added by section 3221(d) of the CARES Act, requiring that the term in this part be given the same meaning as the term for the purposes of the HIPAA regulations.

Comment

Other than the supportive comments discussed above pertaining to the changes to definitions generally, the Department did not receive specific comments for its proposed definition of this term in the regulation.

Response

We appreciate the comments.

Final Rule

The final rule adopts all proposed modifications to the definition of “unsecured protected health information” in § 2.11, without further modification.

Unsecured Record

In the NPRM, the Department explained its view that the proposed addition was necessary to implement

the newly required breach notification standards for part 2 records. To align with the definition of “unsecured protected health information” in the HIPAA regulations at 45 CFR 164.402, the Department proposed to apply a similar concept to records, as defined in this part. Thus, an “unsecured record” would be one that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under Public Law 111–5, section 13402(h)(2).¹⁶⁷

Comment

The Department received one comment from a state government that suggested eliminating “unsecured record,” in favor of “unsecured protected health information” because two terms are unnecessary.

Response

We appreciate the comment but believe both terms are needed to implement the newly required breach notification standards for part 2 records, which are defined differently from PHI.

Final Rule

The final rule adopts all proposed modifications to the definition of “unsecured record” in § 2.11, without further modification.

Use

The Department proposed to add a definition of this term that is consistent with the definition in the HIPAA regulations at 45 CFR 160.103 and as the term is applied to the conduct of proceedings specified in 42 U.S.C. 290dd–2(c). As explained in the NPRM, the Department believes this addition is necessary to more fully align part 2 with the HIPAA regulations’ use of the phrase “use and disclosure,” as well as make clear, where applicable, that many of the activities regulated by this part involve not only disclosures but internal uses of part 2 records by programs or recipients of part 2 records. The Department also proposed this definition to clarify that in this part, the term “use” has a secondary meaning in accordance with the statutory requirements at 42 U.S.C. 290dd–2(c) for “use” of records in civil, criminal, administrative, and legislative investigations and proceedings. The

¹⁶⁷ See U.S. Dep’t of Health and Human Servs., “Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals” (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html>.

Department discusses in greater detail the addition of the term “use” to specific provisions throughout this rule.

Comment

The Department received overwhelmingly supportive comments on the proposed changes throughout this rule to include “use and” preceding “disclosure.” With respect to proposed definitions of “use” and “disclosure,” one commenter stated that the term “use” was broad enough to incorporate both the current understanding (as applied to legal proceedings) and the HIPAA understanding (applied to use of records within a health care entity) without creating confusion and other commenters agreed the proposal would provide clarity. Additionally, several commenters recommended that the Department adopt the HIPAA definitions of “use” and “disclosure” to further align part 2 with the HIPAA regulations. Another commenter suggested further that the final rule eliminate the clause “or in the course of civil, criminal, administrative, or legislative proceedings as described at 42 U.S.C. 290dd–2(c)” because the proposed language departs from the HIPAA definition and is unnecessary.

Response

We appreciate the comments. Although we are declining to adopt the HIPAA definition of “use,” we believe that the definition finalized in this rule is consistent with HIPAA’s definition and with the additional second meaning in this part in accordance with the statutory requirements at 42 U.S.C. 290dd–2(c) for “use” of records in civil, criminal, administrative, and legislative proceedings.

Comment

One commenter, a health system, suggested that the Department revise the definition of “use” within the HIPAA regulations to match the understanding of its meaning as proposed here, to include the initiation of a legal proceeding.

Response

We appreciate this comment, but it is not within the scope of this rulemaking to address the definition of “use” within the HIPAA regulations.

Final Rule

The final rule adopts all proposed modifications to the definition of “use” in § 2.11, without further modification.

Section 2.12—Applicability Proposed Rule

In addition to changes to the use and disclosure language in this section, discussed above, the Department proposed to modify paragraph (a) to update the terminology by replacing “drug abuse” with “substance use disorder.” The Department also proposed to modify paragraph (c)(2) of this section, which excludes from part 2 requirements certain interchanges of information within the Armed Forces and between the Armed Forces and the VA, by replacing “Armed Forces” with “Uniformed Services.” This proposed change would align the regulatory text with the statutory language at 42 U.S.C. 290dd–2(e).

As we noted in the 2021 HIPAA NPRM to modify the HIPAA Privacy Rule, the U.S. Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps share responsibility with the Armed Services for certain critical missions, support military readiness and maintain medical fitness for deployment in response to urgent and emergency public health crises, and maintain fitness for deployment onto U.S. Coast Guard manned aircraft and shipboard missions. Because this part 2 proposal with respect to the Uniformed Services is consistent with the underlying statute, the Department does not believe the modification will change how SUD treatment records are treated for USPHS and NOAA Commissioned Corps personnel, but requested comment on this assumption.

The Department proposed in paragraph (d)(1) of this section to expand the restrictions on the use of records as evidence in criminal proceedings against the patient by incorporating the four prohibited actions specified in 42 U.S.C. 290dd–2(c), as amended by the CARES Act, and expanding the regulatory prohibition on use and disclosure of records against patients to cover civil, administrative, or legislative proceedings in addition to criminal proceedings.¹⁶⁸ Absent patient

¹⁶⁸ Administrative agencies may issue subpoenas pursuant to their authority to investigate matters and several statutes authorize the use of administrative subpoenas in criminal investigations. For example, these may be cases involving health care fraud, child abuse, Secret Service protection, controlled substance cases, inspector general investigations, and tracking unregistered sex offenders. See Charles Doyle, *Administrative Subpoenas in Criminal Investigations: A Brief Legal Analysis*, CRS Report RL33321 (Dec. 19, 2012), <https://crsreports.congress.gov/product/pdf/RL/RL33321>; Legislative investigations may also be conducted in furtherance of the functions of Congress or state

consent or a court order, the proposed prohibitions are: (1) the introduction into evidence of a record or testimony in any criminal prosecution or civil action before a Federal or State court; (2) reliance on the record or testimony to form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency; (3) the use of such record or testimony by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation; and (4) the use of such record or testimony in any application for a warrant.

The Department further proposed changes to paragraph (d)(2) (Restrictions on use and disclosures). In paragraph (d)(2)(i) (Third-party payers, administrative entities, and others), the term “third-party payer” as modified in § 2.11 would have the effect of excluding covered entity health plans from the limits on redisclosure of part 2 records. To clarify the modified scope of this paragraph, the Department proposed to insert qualifying language in § 2.12(d)(2)(i)(A) to refer to “third-party payers, as defined in this part.” This approach implements the CARES Act changes in a manner that preserves the existing redisclosure limitations for any third-party payers that are not covered entities. The modified definition of “third-party payer” in § 2.11 excludes health plans by describing a “third-party payer” as “a person, *other than a health plan as defined at 45 CFR 160.103*, who pays or agrees to pay for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of the patient’s family or on the basis of the patient’s eligibility for Federal, state, or local governmental benefits” [emphasis added]. As a result of the proposal, health plans would be permitted to redisclose part 2 information as permitted by the HIPAA regulations and other “third-party payers” would remain subject to the existing part 2 prohibition on redisclosure.

The Department also proposed to substitute the term “person” for the term “entity” and the phrase “individuals and entities” in § 2.12(d)(2)(i)(B) and (C), respectively. As discussed above in relation to § 2.11 (Definitions), the Department does not intend this to be a substantive change, but rather an alignment with the term as

legislative bodies. See U.S. Dept. of Justice, Off. of Legal Policy, Report to Congress on the Use of Administrative Subpoena Authorities by Executive Branch Agencies and Entities: Pursuant to Public Law 106–544, https://www.justice.gov/archive/olp/rpt_to_congress.htm.

it is defined in the HIPAA Privacy Rule at 45 CFR 160.103.

In addition to these proposed changes to § 2.12(d), the Department requested comment on how the proposed revisions to § 2.33 (Uses and disclosures with written consent), might affect the future data segregation practices of part 2 programs and recipients of part 2 records. We include comments on that topic in this section because it provides the only explicit reference to data segmentation and segregation of records within the regulation. Operationalizing consent for TPO, more narrow consent, revocation of consent, and requests for restrictions on disclosures for TPO may raise challenges concerning tagging, tracking, segregating and segmenting records and health data. These issues are addressed across multiple sections of the final rule, including §§ 2.12, 2.22, 2.31, 2.32, and 2.33.

The Department proposed to conform paragraph (e)(3) of § 2.12 to 42 U.S.C. 290dd–2(c), as amended by section 3221(e) of the CARES Act, by expanding the restrictions on the use of part 2 records in criminal proceedings against the patient to expressly include disclosures of part 2 records and to add civil and administrative proceedings as additional types of forums where use and disclosure of part 2 records is prohibited, absent written patient consent or a court order. Additionally, the Department proposed to clarify language in paragraph (e)(4)(i) of § 2.12, which excludes from part 2 those diagnoses of SUD that are created solely to be used as evidence in a legal proceeding. The proposed change would narrow the exclusion to diagnoses of SUD made “on behalf of and at the request of a law enforcement agency or official or a court of competent jurisdiction” to be used as evidence “in legal proceedings.” The Department believed the proposed clarification would tighten the nexus between a law enforcement or judicial request for the diagnosis and the use or disclosure of the SUD diagnosis based on that request, and requested comment on this approach.

We respond to comments on all aspects of § 2.12 below.

Comment

A few health system commenters supported the proposed change in paragraph (c)(2) to replace Armed Forces with Uniformed Services to be more inclusive.

Response

We appreciate the comments.

Comment

A few commenters expressed concerns about paragraph (c)(6) of this section, which excludes from part 2 applicability the use and disclosure of part 2 records in reports of child abuse and neglect mandated by state law and the fact that the exception does not allow for reporting of vulnerable adult and elder abuse or domestic violence.

Response

Modifications to this provision are outside of the scope of this rulemaking. Moreover, the exception that allows part 2 programs to disclose otherwise confidential records for child abuse reporting is based in a statutory exclusion in 42 U.S.C. 290dd–2(e). Because Congress had the opportunity to address this statutory exclusion in the CARES Act amendments and did not do so we do not believe we can unilaterally expand the exclusion by adding a regulatory exception for elder or vulnerable adult abuse similar to that for child abuse reporting. Congress could in the future choose to add to the statute an exception that would allow part 2 programs to report vulnerable adult and elder abuse and neglect. We further address options for disclosures to prevent harm in the discussion of § 2.20 (Relationship to state laws).

Comment

Some commenters supported the proposed changes in paragraph (d)(2) to the prohibition on use and disclosure of part 2 records against a patient or a part 2 program in investigations and proceedings absent patient consent or a court order. These commenters appreciated the expanded protection from use and disclosure in legislative and administrative investigations and proceedings and the express protection of testimony that conveys information from part 2 records within the consent or court order requirements. Some commenters thought that these express and expanded protections would serve as a beneficial counterweight to easing the flow of part 2 records for health care-related purposes.

Response

We appreciate the comments and agree that the expanded scope of protection to include not only records but testimony and to include legislative and administrative proceedings provides greater protection to patients and part 2 programs that are the subject of investigations and proceedings.

Comment

Many commenters expressed concern about the use of written consent as a

way to overcome the prohibition against the use of records in proceedings against patients, expressing alarm that this could allow coerced consent by law enforcement.

Response

We address the concerns about allowing patient consent for use and disclosure of records in legal proceedings in the discussion of § 2.31 (Consent requirements). Patient consent was not the intended focus of the modifications to § 2.12(d), but was included to mirror the statutory language in 42 U.S.C. 290dd–2(c), as amended by section 3221(e) of the CARES Act. The final rule provides guardrails for the consent process in a new paragraph to § 2.31, discussed below.

Comment

A county board of supervisors commented on changes to paragraph (d)(2), stating that the current regulations require a special court order to authorize the use or disclosure of patient records in a criminal investigation or prosecution. The county expressed concern that a lack of meaningful safeguards when allowing the disclosure of patients' SUD records by patient consent may result in patients being asked to consent to disclosures of their protected SUD treatment records as a condition of a plea deal, sentencing, or release from custody, and that without adequate protections individuals may fear this information being used against them and may not seek treatment. According to the commenter, expanding the ability to access and use patients' SUD treatment records in criminal cases may result in harm to patients such as exacerbation of disparities in access to SUD treatment, criminalization of SUD, and treatment outcomes. The commenter recommended that HHS include meaningful protections in the final rule against patients being coerced into signing consent forms that can be used against them in a criminal or civil case.

Response

We have added at § 2.31(d) an express requirement that consent for use and disclosure of records in civil, criminal, administrative, and legislative investigations and proceedings be separate from consent to use and disclose part 2 records for other purposes. The existing rule, at § 2.33(a), permits patients to consent to use and disclosure of their records and that part 2 programs may disclose the records according to the consent. We interpret

this to include consent for use and disclosure of records in legal proceedings, including those that are brought against a patient. Thus, we do not view this final rule's language about consent in § 2.12(d) as creating a substantive change to patients' rights or the existing procedures for legal proceedings, but as clarifying how consent is one option for achieving the use and disclosure of records in proceedings against a patient.

Nonetheless, because the role of patient consent is expanding, we created the new requirement for separate consent as § 2.31(d) in response to many comments about the potential for coerced consent and specific suggestions about ways to reduce instances of potential coercion, including requiring it to be separate from TPO consent or consent to treatment. This paragraph provides that patient consent for use and disclosure of records (or testimony relaying information contained in a record) in a civil, criminal, administrative, or legislative investigation or proceeding cannot be combined with a consent to use and disclose a record for any other purpose. Some commenters asserted that patients are particularly vulnerable to coerced consent at the initiation of treatment when they are suffering the effects of SUD and that they may not fully appreciate how their records may be used or disclosed in proceedings against them. Thus, requiring separate consent for use or disclosure of records in investigations or proceedings against a patient would help ensure that patients are better aware of the nature of the proceedings and how their records may be used. Signing a separate document specific to one purpose draws attention to the consent decision and provides greater opportunity for review of the nature of the consent. Comments about the proposed changes for legal proceedings are also addressed in §§ 2.2, 2.31, 2.66, and 2.67. Additional comments with similar concerns are discussed in § 2.31.

Comment

With respect to the applicability of part 2 to third-party payers, we received overwhelming support from the several organizations that commented on the proposed changed definition of third-party payer as applied in paragraph (d)(2)(i) of this section. These commenters supported the proposal to distinguish health plans, which are covered entities, from other third-party payers who are subject to part 2 (but not subject to HIPAA). One commenter explained their understanding that covered entity payers (*e.g.*, health plans)

would already be included in the meaning of covered entity for the purposes of part 2 and HIPAA, and therefore able to operate under the relaxation of the redisclosure prohibition for TPO purposes while "third-party payers" under this narrowed definition would not. The commenter stated its belief that the change was an important and useful clarification of the continued redisclosure prohibition on treatment uses by such third-party payers.

A few HIE/HIN commenters strongly supported this change because the inability to segment the part 2-protected claims/encounter data from the non-part 2 data has often been a barrier to health plans contributing the clinical component of this administrative data to local, regional, and national HIE efforts. Additionally, a health system requested that the Department ensure that ACOs and population health providers have access to full part 2 information without a beneficiary having to explicitly opt-in to data sharing.

Response

We appreciate the comments concerning how the proposed narrower definition of "third-party payer" operates in paragraph (d)(2) of this section. Applicability to health plans is now addressed under paragraph (d)(2)(C) within the reference to covered entities. Additionally, the new statement in paragraph (d)(2)(C) in this final rule provides that health plans are not required to segregate records or segment data upon receipt from a part 2 program. ACOs and population health providers will need to evaluate the applicability provision based on their status as covered entities or business associates.

Comment

A medical professionals association voiced its strong support for data segmentation in support of data interoperability while maintaining patient privacy; capabilities for EHRs to track and protect sensitive information before it can be disclosed or redisclosed; and continuous monitoring and data collection regarding unintended harm to patients from sharing their sensitive information.

Response

We appreciate the comment about improving the capabilities for EHRs to segment data to maintain patient privacy while also remaining interoperable. The final rule change expressly stating that data segmentation is not required by recipients under a TPO consent does not preclude the

voluntary use of data segmentation or tracking as means to protect sensitive data from improper disclosure or redisclosure. As a result of the modifications to paragraph (d)(2) of § 2.12, key recipients of part 2 records may choose the best method for their health IT environment and organizational structure to protect records from use and disclosure in legal proceedings against the patient, absent consent or a court order. For example, the use of the data segmentation for privacy ("DS4P") standard as adopted as part of the ONC Health IT Certification Program criteria in 45 CFR 170.315(b) is a technical capability that would be acceptable/sufficient.¹⁶⁹

Comment

A few individual commenters, a police and community treatment collaborative, a health IT vendor, and an SUD recovery policy organization, requested changes to paragraph (e)(4), which applies to a "[d]iagnosis which is made on behalf of and at the request of a law enforcement agency or official or a court of competent jurisdiction solely for the purpose of providing evidence[.]" Specifically, they recommended in § 2.12(e)(4)(i) that we add language to include the purpose of determining eligibility for participation in deflection, diversion, or reentry alternatives to incarceration. The commenters stated that alternatives to incarceration require swift assessments, diagnoses, and referrals to treatment and care, and that the requested change is narrowly tailored and consistent with best practice and priorities within the justice field.

Response

We decline to further modify paragraph (e)(4) in the manner suggested, although we appreciate the comment and the intent to support criminal justice deflection programs and alternatives to incarceration where appropriate. The changes we proposed to this paragraph were for clarification and not intended to create substantive modifications. However, we believe that as drafted, the final regulatory language supports the disclosure of diagnoses made for the purpose of providing evidence for any number of purposes, which could include determining eligibility for participation in deflection, diversion, or reentry alternatives to incarceration. Thus, in our view, the

¹⁶⁹ See The Off. of the Nat'l Coordinator for Health Info. Tech., "Certification Companion Guide: Security tags" (2015), <https://www.healthit.gov/test-method/security-tags-summary-care-send>.

suggested change is not necessary to meet the commenter's purposes.

Final Rule

The final rule adopts all proposed changes to § 2.12 and further modifies this section by: (1) clarifying that the restrictions on uses and disclosures of records in proceedings against a patient apply to persons who receive records from not only part 2 programs and lawful holders, but also from covered entities, business associates, and intermediaries to allow for the new operation of consent as enacted by the CARES Act;¹⁷⁰ (2) modifying paragraph (b)(1) by replacing “Armed Forces” with “Uniformed Services” to conform with the changes in paragraph (c)(2) and the statutory language at 42 U.S.C. 290dd–2(e); (3) adding an express statement to paragraph (d)(2)(i)(C) that recipients of records under a TPO consent who are part 2 programs, covered entities, and business associates are not required to segregate the records received or segment part 2 data; and (4) removing a phrase in paragraph (d)(2)(ii) that implied a requirement for recipients of part 2 records to segregate or segment the data received, including removing the requirement from covered entities, business associates, and intermediaries, as well as from part 2 programs.

Section 2.13—Confidentiality Restrictions and Safeguards

Proposed Rule

The current provisions of this section apply confidentiality restrictions and safeguards to how part 2 records may be “disclosed and used” in this part, and specifically provide that part 2 records may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings. The current provisions also provide that unconditional compliance with part 2 is required by programs and lawful holders and restrict the ability of programs to acknowledge the presence of patients at certain facilities. Changes to the Department's use of terms “use” and “disclose” in this section are discussed above. Paragraph (d) of § 2.13 (List of disclosures), includes a requirement for intermediaries to provide patients with a list of entities to which an intermediary, such as an HIE, has disclosed the patient's identifying information pursuant to a general designation. The Department proposed to remove § 2.13(d) and redesignate the content as § 2.24, change the heading of

§ 2.24 to “Requirements for intermediaries,” and in § 2.11 create a regulatory definition of the term “intermediary” as discussed above. The Department's proposal to redesignate § 2.13(d) as § 2.24 would move the section toward the end of subpart B (General Provisions), to be grouped with the newly proposed §§ 2.25 and 2.26 about patient rights and disclosure. Section 2.24 is discussed separately below.

In addition to these proposed structural changes, the Department also proposed minor wording changes to paragraphs (a) through (c) of § 2.13 to clarify who is subject to the restrictions and safeguards with respect to part 2 records. The Department solicited comment on the extent to which part 2 programs look to the HIPAA Security Rule as a guide for safeguarding part 2 electronic records. The Department also requested comment on whether it should modify part 2 to apply the same or similar safeguards requirements to electronic part 2 records as the HIPAA Security Rule applies to ePHI or whether other safeguards should be applied to electronic part 2 records.

Comment

We received general support from an HIE regarding our efforts to align the security requirements in part 2 for EHRs with the HIPAA Security Rule. An individual commenter said that similar safeguard requirements should apply to electronic part 2 records as the HIPAA Security Rule applies to ePHI. The commenter stated that, ideally, stronger safeguards should apply to electronic part 2 records because these records can function as a bridge to discrimination, sanctions, and adverse actions. An insurer commenter stated that it manages electronic part 2 records and information consistent with the HIPAA Security Rule currently and would—in keeping with the concept of treating SUD information the same as other PHI—support applying the same rules and protections of the HIPAA Security Rule to electronically stored and managed part 2 records and information. Noting that the HIPAA Privacy and Security Rules are widely adopted across the health care continuum, an HIE association encouraged the Department to pursue further alignment with HIPAA Security Rule requirements where appropriate. Another health insurer supported aligning part 2 safeguards with the safeguards applicable under the HIPAA regulations. This commenter stated that, as HHS works to align part 2 regulations with HIPAA regulations, the ultimate goal should be to streamline policies

while ensuring the protection of patient data across programs and data sharing platforms. The health plan and another commenter, a health insurer, believed that different types of PHI should share the same level of protection and supports Department efforts toward this end.

Response

We appreciate the comments on our proposed changes and comments on modifying part 2 to apply the same or similar safeguard requirements to electronic part 2 records as apply to the HIPAA Security Rule. Prior to our changes in this final rule, part 2 programs and other lawful holders already were required to have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information. The provisions applied to paper records and electronic records.

Consistent with the amendment enacted in the CARES Act and codified at 42 U.S.C. 290dd–2(j), the final rule applies breach notification requirements to “unsecured records” in the same manner as they currently apply to “unsecured PHI” in the Breach Notification Rule, including specific requirements related to the manner in which breach notification is provided. We are not making any additional modifications to align the HIPAA Security Rule and part 2 at this time, but will take these comments into consideration in potential future rulemaking.

Comment

A few HIEs/HIE associations urged the Department to add new language to § 2.13 that expressly provides: “[c]onsent revocation. If a patient revokes a consent, the consent revocation is only effective to prevent additional disclosures from the part 2 program(s) to the consent recipient(s). A recipient is not required to cease using and disclosing part 2 records received prior to the revocation.”

The commenters believed that adding this language to § 2.13 would mitigate part 2 program concerns that they might be held accountable for a recipient's continued use and disclosure of previously disclosed part 2 program records. The Department sought comment on whether it should require part 2 programs to inform an HIE when a patient revokes consent for TPO so that additional uses and disclosures by the HIE would not be imputed to the

¹⁷⁰ The non-substantive wording changes to paragraphs (a), (c), and (e) are included in the amendatory language in the last section of this final rule.

programs that have disclosed part 2 records to the HIE. These commenters responded that requiring such notification would directly contradict the Department's statements in the preamble to the NPRM—and the purpose of the CARES Act—because a notification implies that it would be unlawful for the HIE to continue to use and disclose the part 2 records it received prior to revocation. A better approach according to these commenters would be to clarify in the part 2 regulations what is and is not permitted after a revocation.

Response

Revocation of consent is associated with a patient's wish to modify or rescind previously granted written consent provided under § 2.31 in subpart C. We do not agree that stating revocation requirements in this section would clarify these requirements and those issues are addressed in the discussion of § 2.31.

Comment

A medical professionals association generally supported the alignment of redisclosure processes with HIPAA. The commenter also supported prohibiting redisclosures of records for use in civil, criminal, administrative, and legal proceedings. Along with increased patient and provider education about disclosure and data protection, the association further encouraged the Department to support the development of technological infrastructure to manage these data once disclosed.

Response

We appreciate this comment on the Department's proposed changes. We have revised the part 2 redisclosure requirements to align more closely with HIPAA requirements with respect to disclosures of PHI. We clarify applicability of these changes to business associates and covered entities. Subject to limited exceptions, such as redisclosed records cannot be used in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority against the patient, unless authorized by the consent of the patient.

Final Rule

The final rule adopts the changes to § 2.13 as proposed, including removing paragraph (d) and redesignating it as § 2.24 (Requirements for intermediaries).¹⁷¹

¹⁷¹ The changes to the remaining provisions of § 2.13 are non-substantive and are included in the amendatory language in the last section of this final rule.

Section 2.14—Minor Patients

Proposed Rule

The Department proposed to change the verb “judges” to “determines” to describe a part 2 program director's evaluation and decision that a minor lacks decision making capacity, which can lead to a disclosure to the patient's parents without the patient's consent. This change is intended to distinguish between the evaluation by a part 2 program director about patient decision making capacity and an adjudication of incompetence made by a court, which is addressed in § 2.15. The Department also proposed a technical edit to § 2.14(c)(1) to correct a typographical error from “youthor” to “youth or.”

The Department also proposed to substitute the term “person” for the term “individual” in § 2.14(b)(1) and (2), (c) introductory text, and (c)(1) and (2), respectively.

Overview of Comments

The Department received general support for its proposed changes to § 2.14. However, some commenters expressed concern about certain proposed changes or requested additional clarity, as described below.

Comment

An HIE association urged the Department to align the part 2 requirements regarding minors with the state-based requirements regarding minor access, consent, and disclosure of their health records. The commenter noted that some states have stringent rules for when a minor patient can control different sections of their health record and urged the Department to engage with patient advocacy organizations to fully understand the implications of the minor consent provisions in part 2.¹⁷² Another commenter noted that jurisdictions vary with respect to the age of majority, who is considered a legal guardian or authorized representative, emancipated minors, and specific consent for special health services (e.g., HIV testing, reproductive services, mental and behavioral health). Commenters cited examples of states such as California, which they perceived to have strong consent and privacy provisions for minors and argued that it was important that part 2 foster alignment between consent to receive care and access to medical information by the person

¹⁷² See, e.g., Marianne Sharko, Rachael Jameson, Jessica S. Ancker, et al., “State-by-State Variability in Adolescent Privacy Laws,” *Pediatrics* (May 9, 2022), <https://doi.org/10.1542/peds.2021-053458>.

authorized to provide consent to treatment.

Response

We acknowledge that regulations and statutes pertaining to behavioral health, including treatment and access to records by those who consent, differ by state.¹⁷³ The Department has previously highlighted that § 2.14 states that “these regulations do not prohibit a part 2 program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a state or local law requiring the program to furnish the service irrespective of ability to pay.”¹⁷⁴ State laws may also vary with respect to access to records by parents or caregivers. As provided in § 2.20 (Relationship to state laws), part 2 “does not preempt the field of law which they cover to the exclusion of all state laws in that field.” Thus, states may impose requirements for consent, including for minors, that are more stringent than what Federal regulations may require. The Department understands that there exist variations among jurisdictions concerning minor and parent or guardian consent requirements. Part 2 programs and other regulated entities are advised to seek legal advice on the application of their state and local laws when appropriate.

Comment

One commenter urged the Department to proactively partner with states to design state-specific educational resources and tools to expedite access to SUD treatments. The commenter cited as one example the New York Civil Liberties Union 2018 pamphlet entitled “Teenagers, Health Care and the Law: A Guide to Minors' Rights in New York State” as one helpful resource.¹⁷⁵ Other commenters also urged the Department to provide guidance about minor consent in relation to Medicaid, the Children's Health Insurance Program (CHIP), and other health coverage programs.

Response

The Department appreciates examples of what commenters view as relevant or

¹⁷³ *Id.* See also “TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations,” *supra* note 122. See also, 82 FR 6079 (Jan. 18, 2017).

¹⁷⁴ 82 FR 6052, 6083.

¹⁷⁵ New York Civil Liberties Union, “Guide: Teenagers, Health Care, and the Law (English and Spanish)” (Oct. 2, 2018), <https://www.nyclu.org/en/publications/guide-teenagers-health-care-and-law-english-and-spanish>.

helpful resources and publications but does not necessarily endorse the content of specific publications not developed or reviewed by HHS. We will consider what additional guidance from HHS may be helpful after this rule is finalized.

Comment

Commenters generally supported the proposed change from “judges” to “determines” to better distinguish a part 2 program director’s evaluation and decision that a minor lacks decision-making capacity from when a court adjudicates (*i.e.*, judges) a patient as lacking decision-making capacity. But one association noted that in addition to the Federal regulation, states can also have their own requirements related to minors, decision-making capacity, and their ability to make independent decisions regarding care and treatment. The commenter believed that part 2 programs, consumers, and other stakeholders could benefit from the Department discussing the Federal standard in the preamble to final regulations or in future guidance discussing how states can align with the standard and potential areas for Federal and state conflicts. Other commenters also urged the Department to provide additional guidance on the intersection of state and Federal laws, including for minors out of state and receiving SUD treatment.

Response

The Department appreciates the comments about changing “judges” to “determines” and will consider what additional guidance on these issues may be helpful after this rule is finalized.

Comment

Commenters supported the proposal to remove the term “incompetent” and instead refer to patients who lack the capacity to make health care decisions to distinguish between lack of capacity and adjudication of incompetence.

Response

The Department appreciates the comments on this proposed change.

Comment

Commenters emphasized the importance of minors being able to control their health records but also ensuring that parents and guardians do not face unnecessary barriers to obtaining SUD treatment for youth in their care. Providers, one commenter asserted, are reluctant or even unwilling to include parents and guardians in treatment, even when their clinical judgment would dictate otherwise.

Response

The Department agrees that it is important for minors to have input concerning the use and disclosure of their health records in a manner that is consistent with state law. The Department also has emphasized both with respect to HIPAA and part 2 that parents, guardians, and other caregivers should not face unnecessary barriers in supporting a loved one’s care.¹⁷⁶ SAMHSA has published resources for families coping with mental health and SUDs and OCR has issued guidance for consumers and health professionals on HIPAA and behavioral health.¹⁷⁷

Comment

To allow for meaningful care coordination for minors, a state agency urged the Department to modify proposed § 2.14(b)(2) as follows: “[w]here state law requires parental consent to treatment, any consent required under this Part may be given by the minor’s parent, guardian, or other person authorized under state law to act on the minor’s behalf only if: * * *.”

Response

We appreciate the suggestion; however, because we did not propose modifications to this language or request public comment related to it, making this change would be outside the scope of this rulemaking. For purposes of this rulemaking, finalizing the existing language, without modification, accurately reflects the current balance between part 2 confidentiality requirements and state legal requirements concerning minor consent.

Comment

One commenter expressed concern that, in their view, part 2 provides no options for part 2 providers to involve parents or guardians in a minor’s treatment without the minor’s consent, even where state law explicitly permits such involvement or even requires providers to make determinations about the appropriateness of a parent or guardian’s involvement. The commenter urged the Department to align § 2.14

¹⁷⁶ See “Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE),” *supra* note 150; U.S. Dep’t of Health and Human Servs., “Personal Representatives and Minors,” <https://www.hhs.gov/hipaa/for-professionals/faq/personal-representatives-and-minors/index.html>.

¹⁷⁷ See Substance Abuse and Mental Health Services Administration, “Resources for Families Coping with Mental and Substance Use Disorders” (Mar. 14, 2023), <https://www.samhsa.gov/families>; U.S. Dep’t of Health and Human Servs., “The HHS Office for Civil Rights Responds to the Nation’s Opioid Crisis” (Mar. 11, 2021), <https://www.hhs.gov/civil-rights/for-individuals/special-topics/opioids/index.html>.

with provisions in the Privacy Rule permitting access to treatment records if a minor consents to care as provided under state law.

Response

The Department acknowledges the complexity of the intersection of part 2 and state requirements concerning minor consent, including parental or caregiver involvement. After this rule is finalized, the Department may provide additional guidance on these issues. Part 2, in part, provides that “[w]here state law requires consent of a parent, guardian, or other individual for a minor to obtain treatment for a substance use disorder, any written consent for disclosure authorized under subpart C of this part must be given by both the minor and their parent, guardian, or other individual authorized under state law to act in the minor’s behalf.” The Department has published relevant resources for families and guidance on applying behavioral health privacy laws to mental health and SUDs.¹⁷⁸

Comment

With respect to the role of part 2 program director, one association of medical professionals asserted that the decision-making of a minor should be made in consultation with the treatment plan team and not in isolation by a part 2 program director.

Response

The Department appreciates this input on clinician-based decisions about patients. While the part 2 program director has specific responsibilities under this section, the Department would expect most part 2 programs to have protocols detailing the program director’s role and consultation with others on the treatment team as needed. As the person with authority over the part 2 program, the director would be responsible for how the program operates, so we do not view additional regulatory requirements as necessary.

Final Rule

The Department is finalizing all proposed changes to § 2.14 without further modification. This includes a technical edit in § 2.14(c)(1) to correct a typographical error from “youthor” to “youth or” and changing the verb “judges” to “determines” to describe a part 2 program director’s evaluation and decision that a minor lacks decision making capacity that could lead to a

¹⁷⁸ See, e.g., The Ctr. of Excellence for Protected Health Info., “Families and minors,” <https://coephi.org/topic/families-and-minors/>.

disclosure to the patient's parents without the patient's consent.

Section 2.15—Patients Who Lack Capacity and Deceased Patients

Proposed Rule

The Department proposed to replace outdated terminology in this section that referred to “incompetent” patients, refer to the “use” of records in addition to disclosures, and to substitute the term “person” for the term “individual” as discussed above in relation to § 2.11 (Definitions). The Department further proposed to clarify that paragraph (a) of this section refers to a lack of capacity to make health care decisions as adjudicated by a court while paragraph (b) refers to lack of capacity to make health care decisions that is not adjudicated by a court, and to add health plans to the list of entities to which a part 2 program may disclose records without consent to obtain payment during a period when the patient has an unadjudicated inability to make decisions. We also proposed updates to paragraph (b) of this section concerning consent by personal representatives.

Comment

A health plan commenter supported inclusion of health plans to the list of entities to which a part 2 program can disclose records when a patient lacks capacity. An association of medical professionals also supported adding health plans to the list of entities to which a part 2 program may disclose records without consent when a patient lacks capacity to make health care decisions to ensure that part 2 programs receive appropriate and timely payment for their services. A health system expressed general support for our proposed changes.

Response

We appreciate the comments on the proposed changes.

Comment

An association of medical professionals supported the proposed change from “incompetent patients” to “patients who lack capacity to make health care decisions,” whether adjudicated or not. The commenter also supported the addition of health plans to the list of entities to which a program may disclose records without consent. The commenter also said that families often request the records of deceased patients and there does not appear to be a consistent policy about this among SUD treatment centers. It would be helpful to have this matter addressed.

Response

We appreciate the comment on our proposed changes. With respect to deceased patients, part 2 regulations as finalized “do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.” Additionally, the regulations state that “[a]ny other use or disclosure of information identifying a deceased patient as having a substance use disorder is subject to the regulations in this part. If a written consent to the use or disclosure is required, that consent may be given by the personal representative.” In the preamble for § 2.11 of this rule, we discuss applying the HIPAA definition of “personal representative.” We have stated in guidance for the HIPAA Privacy Rule that “[s]ection 164.502(g) provides when, and to what extent, [a] personal representative must be treated as the individual for purposes of the [HIPAA Privacy] Rule.”¹⁷⁹ Section 164.502(g)(2) requires a covered entity to treat a person with legal authority to act on behalf of an adult or emancipated minor in making decisions related to health care as the individual's personal representative with respect to PHI relevant to such personal representation.¹⁸⁰ The definition in this rule mirrors language in the HIPAA Privacy Rule at 45 CFR 164.502(g).

Comment

An association of medical professionals supported the proposed changes but urged the Department to reduce confusion and avoid potential conflicts with state law by amending § 2.15(b)(2) to clarify that this section only applies if there are no applicable state laws governing surrogate decision making.

Response

We decline to modify this section to refer to state law requirements, as we discuss intersections with state law in § 2.20 and we do not anticipate that the definition of “personal representative,” which mirrors the standard in the HIPAA regulations, will conflict with state law requirements.

Comment

One commenter believed that even though the NPRM addressed the issue of

a patient's lack of capacity to sign an informed consent, it failed to address circumstances involving diminished capacity associated with intoxication, withdrawal, medication induction, and early phases of treatment. The commenter asserted that addressing the issue of temporary diminished capacity is critical to the proposed perpetual consent for TPO purposes promoted by the NPRM. The commenter also stated that relying on a single enduring consent made at a time when a person is most vulnerable and cognitively compromised is unethical, and that a signed consent around the time of treatment entry should be valid for no more than six months. According to this commenter, it is important to stress that the authority of the part 2 program director to exercise the right of the patient to consent to uses and disclosures of their records is restricted to that period where the patient suffers from a medical condition that creates a lack of capacity to make knowing or effective health care decisions on their own behalf. Further, according to this commenter, that authority is limited to obtaining payment for services from a third-party payer or health plan, and should not extend more than 30 days. After such time, the part 2 program director should seek a court order, according to the commenter.

Response

We agree with the commenter that, as stated in the regulation, the part 2 program director's authority in § 2.15(a)(2) extends only to obtaining payment for services from a third-party payer or health plan.

In some cases, a patient who has diminished capacity due to overdose, intoxication, withdrawal, or other medical conditions may be considered by a medical provider to be experiencing a “bona fide medical emergency in which the patient's prior written consent cannot be obtained.”¹⁸¹ As the Department explained in preamble to its final 2020 rule,¹⁸² under § 2.51, disclosures of SUD treatment records without patient consent are permitted in a bona fide medical emergency. Although not a defined term under part 2, a “bona fide medical emergency” most often refers to the situation in which an individual requires urgent clinical care to treat an immediately life-threatening condition (including, but not limited to, heart attack, stroke, overdose), and in which it is infeasible to seek the individual's consent to release of relevant, sensitive

¹⁷⁹ U.S. Dep't of Health and Human Servs., “Personal Representatives” (Sept. 19, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html>.

¹⁸⁰ *Id.* See also, “Personal Representatives and Minors,” *supra* note 176.

¹⁸¹ See 42 CFR 2.51 (Medical emergencies).

¹⁸² 85 FR 42986, 43018.

SUD records prior to administering potentially life-saving care. In such cases, the medical emergency provisions of part 2 would apply.

In addition, provisions of § 2.31 (Consent requirements), are pertinent to this comment. Section 2.31(a)(6) of this final rule requires that the consent must inform the patient of “[t]he patient’s right to revoke the consent in writing, except to the extent that the part 2 program, or other lawful holder of patient identifying information that is permitted to make the disclosure, has already acted in reliance on it, and how the patient may revoke consent.” Thus, a patient, after their medical condition has been treated, will be able to modify any part 2 written consent at a later date.

Comment

An academic health system believed that under § 2.15(a)(2), patients who may lack capacity temporarily, without court intervention, have no one with the legal authority to consent to uses or disclosures other than for payment purposes. The commenter viewed this restriction as inconsistent with both state law and HIPAA and as an outdated and problematic limitation. The commenter said that at times its part 2 programs admit a patient who lacks capacity temporarily (where there is no need for court intervention) and permit a surrogate to consent to treatment as permitted by state law, particularly in the inpatient context. The commenter added, the regulations should reflect that if a surrogate or personal representative has the ability under state law to consent to treatment, then that same surrogate or personal representative should have the ability to consent to the use and disclosure of part 2 records regardless of whether there has been an adjudication by a court. Otherwise, part 2 programs would be admitting a patient into treatment with no one who has the legal authority to consent to critical uses or disclosures that are essential or legally required to operate the part 2 program. According to the commenter, making this change would also better align part 2 with HIPAA and the concept that a personal representative has authority under state law to consent to both treatment and the uses and disclosures of information related to that treatment.

Response

We refer the commenter to our responses above regarding the part 2 medical emergency provisions that may apply to such circumstances and to our comments on the definition of personal

representative. We discuss intersections with state law in § 2.20.

Comment

A commenter anticipated that once the proposed rule is finalized, part 2 programs will begin to utilize existing technologies and workflows that have been created to comply with HIPAA standards. The commenter stated that many part 2 programs may require all patients to sign a global consent as a condition of treatment to take advantage of these current technologies and workflows that will now be available to part 2 programs. The commenter expressed concern that, once these part 2 programs change their practices to align with existing technologies and workflows, there would be no mechanism for a part 2 program to treat a patient who refuses to sign a global consent. The commenter suggested that the “payment only” limitation in § 2.15(a)(2) would prevent part 2 programs from offering treatment to those most vulnerable patients because no one will have the authority to consent to the use and disclosure of part 2 information. Having a patient admitted into a part 2 program with no one able to provide TPO consent that would permit subsequent beneficial redisclosures, may penalize patients who are most in need of treatment, according to this commenter.

Another commenter, a health plan association, also urged HHS to allow the part 2 program director to exercise the patient’s right to consent to any use or disclosure under part 2 when the patient is incompetent but not yet adjudicated by a court as such. The commenter stated that the rule should not deprive incompetent persons most in need of care from the ability to access care and expressed particular concern about circumstances in which a part 2 program may be the only mental health provider in the area (e.g., in rural locations). The commenter stated that part 2 should not prevent part 2 programs from divulging information without which the incompetency adjudication process cannot proceed; otherwise, part 2 would create a barrier to access to care for incompetent patients because the information the part 2 program has might be the only information that would enable an adjudication of incompetence. The “medical emergency” exception, the commenter asserted, would sometimes be of little use if the emergency providers to whom information is disclosed cannot obtain consent to render care, and a court adjudication of incompetency is impossible to achieve without part 2 program information.

Additionally, the commenter found that the proposed rule did not address advance directives like durable powers of attorney that do not involve court adjudication but physician adjudication to trigger the provisions conferring authority to the patient’s personal representative. Therefore, according to the commenter, § 2.15(a)(2) should read: “[i]n the case of a patient, other than a minor or one who has been adjudicated as lacking the capacity to make health care decisions, that for any period suffers from a medical condition that prevents knowing or effective action on their own behalf, the part 2 program director may exercise the right of the patient to consent to a use or disclosure under subpart C of this part.”

Response

As noted above, the part 2 medical emergency provisions may apply to the circumstances described by the commenter if a patient cannot consent to treatment due to a bona fide medical emergency. Absent a medical emergency, under § 2.15(a)(2) the part 2 program director may exercise the right of the patient to consent to disclosure for the sole purpose of obtaining payment for services from a third-party payer for an adult patient who for any period suffers from a medical condition that prevents knowing or effective action on their own behalf. Consistent with the Privacy Rule’s provisions on personal representatives, we state in § 2.11 that a personal representative means a person who has authority under applicable law to act on behalf of a patient who is an adult or an emancipated minor in making decisions related to health care. Also, consistent with the Privacy Rule, a personal representative under part 2 would have authority only with respect to patient records that are relevant to such personal representation.

Comment

A state agency recommended modifying § 2.15(a) to specifically address adult patients who lack capacity, but have appointed a personal representative. This change, according to the commenter, would allow for better care and coordination for patients who have a personal representative.

Response

We believe our modifications to § 2.15(a) as finalized in this rule respond to the commenter’s concerns about the role of the personal representative. We decline to make additional changes to this section as requested by the commenter because the

new definition of “personal representative” defers to state law.

Comment

A health plan commenter stated that when a patient has an adjudicated inability to make decisions due to a medical condition, this section of the final rule should clarify that patients would be allowed to request that their billing information not be sent to a health plan if the patient (or third party other than the health plan) agrees to pay for services in full. The commenter also expressed concern about a general lack of guidance on how proof of an adjudicated inability to make decisions (other than in an emergency) would be documented and sought further clarification. The commenter asked the Department to confirm that a health plan would not be required to (1) confirm how consent was obtained and (2) treat SUD information of patients who lack capacity in a special manner—for example, through specialized documentation and other procedures—or differently from information of patients who directly provided consent. The commenter said that these changes would help facilitate treatment and payment for patients who lack capacity temporarily, which may lead to more timely care and better outcomes. According to this commenter, relying on a part 2 program’s director expertise to determine the patient’s present capacity would facilitate more timely care decisions and reduce burden on health plans.

Response

We discuss consent provisions elsewhere in this rule. We confirm that this final rule does not create new requirements for special or unique treatment of SUD information of patients who lack capacity.

As we discuss above, when a patient suffers from a medical condition that prevents knowing or effective action on their own behalf for any period, the part 2 program director may exercise the right of the patient to consent to a use or disclosure under subpart C for the sole purpose of obtaining payment for services from a third-party payer or health plan. If a part 2 program director believes that this step is unnecessary after speaking with the patient or others, the director may choose not to exercise this right. If a patient has an adjudicated inability to make decisions due to a medical condition that prevents them from knowing or taking action, he or she may be unable to consent to or refuse consent to a use or disclosure for the sole purpose of obtaining payment for services from a

third-party payer or health plan; in such circumstances, the part 2 program director’s ability to exercise the patient’s right to consent for the sole purpose of obtaining payment may apply.

Final Rule

In addition to finalizing changes such as replacing “individual” with “person” and referring to “use” in addition to “disclosures,” we are finalizing the proposal to remove the term “incompetent” in this section and refer instead to patients who lack capacity to make health care decisions. We also are finalizing the proposal to clarify that paragraph (a) of this section refers to lack of capacity to make health care decisions as adjudicated by a court while paragraph (b) refers to lack of capacity to make health care decisions that is not adjudicated, and to add health plans to the list of entities to which a part 2 program may disclose records without consent to obtain payment during a period when the patient has an adjudicated inability to make decisions. We also are finalizing updates to paragraph (b) of this section concerning deceased patients and consent by personal representatives.

Section 2.16—Security for Records and Notification of Breaches

Overview of Rule

Section 2.16 (Security for records) contains several requirements for securing records. Specifically, § 2.16(a) requires a part 2 program or other lawful holder of patient identifying information to maintain formal policies and procedures to protect against unauthorized uses and disclosures of such information, and to protect the security of this information. Section 2.16(a)(1) and (2) set forth minimum requirements for what these policies and procedures must address with respect to paper and electronic records, respectively, including, for example, transfers of records, maintaining records in a secure location, and appropriate destruction of records. Section 2.16(a)(1)(v) requires part 2 programs to implement formal policies and procedures to address removing patient identifying information to render it non-identifiable in a manner that creates a low risk of re-identification.

The current part 2 requirements for maintaining the security of records are limited to these provisions requiring policies and procedures. In contrast, the HIPAA regulations include a HIPAA Security Rule with specific standards and implementation specifications for how covered entities and business associates are required to safeguard

ePHI. Part 2 does not have similar requirements.

Application of Part 2 Security Requirements to Lawful Holders

Current § 2.16 applies security requirements to part 2 programs and lawful holders. The term “lawful holder” is a recognized term that is applied in several part 2 regulatory provisions; however, it is not defined in regulation. Generally, it refers to “an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure) or as a result of one of the exceptions to the consent requirements in the statute or implementing regulations and, therefore, is bound by 42 CFR part 2.”¹⁸³

The Department sought public comment on whether security requirements should apply uniformly across all persons who receive part 2 records pursuant to consent such that certain failures, such as a failure to have “formal policies and procedures” or to “protect” against threats, would result in the imposition of civil or criminal penalties again all persons who receive these records pursuant to consent. The Department’s request for comment in this regard asked, “whether the requirements of this section that apply to a lawful holder should in any way depend on the level of sophistication of a lawful holder who is in receipt of Part 2 records by written consent, or should depend on whether the lawful holder is acting in some official or professional capacity connected to or related to the Part 2 records.”

Comment

One commenter, an association, of medical professionals, opined that all entities that hold personal health information should be required to notify persons when their information is breached, but also that breach rules must not hold parties responsible for the actions of other parties over whom they do not have control.

Response

We agree with the sentiments expressed in this comment and assume that the commenter’s use of the term “entity” is referring to an organizational or professional entity and not an individual acting in a personal capacity. The final rule requires part 2 programs to provide breach notification for breaches of part 2 records in the same manner as breach notification is

¹⁸³ See 82 FR 6052, 6068; See also 81 FR 6988, 6997.

required for breaches of PHI, which would include breaches of part 2 records held on behalf of a program by QSOs or business associates. Under HIPAA, a business associate is required to notify a covered entity of breaches and we believe part 2 programs that are not covered entities could obligate their QSOs to notify the programs of breaches through contractual provisions. A part 2 program would not be responsible for breaches by QSOs or business associates. However, the part 2 program is responsible under this rule for having in place contractual requirements to ensure that it is timely notified of a breach by such entities so that it can meet its obligations to notify affected individuals.

Comment

A few commenters, including a managed care organization and a county health department, opined that it is appropriate to apply breach notification requirements to QSOs. Another commenter, a health plan, requested confirmation from the Department that the part 2 breach notification requirements are the same as the requirements under the HIPAA Breach Notification Rule, and also sought confirmation that the requirements would not apply to lawful holders who are caregivers not acting in a professional capacity.

Response

Our close review of the statute leads us to believe that there is no authority to apply notification requirements to QSOs as they are applied to business associates under the HIPAA Breach Notification Rule. We also agree that non-professional lawful holders, such as family members, friends, or other informal caregivers, are not the same as lawful holders acting in a professional capacity. However, non-professionals should nonetheless take reasonable steps to protect records in their custody.

Final Rule for Lawful Holders and Security of Records

We are re-organizing § 2.16(a) and finalizing additional language to clarify to whom the security requirements apply. Specifically, we are creating a new exception for certain lawful holders in new paragraph (a)(2) that expressly excludes “family, friends, and other informal caregivers” from the requirements to develop formal policies and procedures. We expect that informal caregivers and other similar lawful holders who would be subject to this exception still recognize some responsibility to safeguard these sensitive records and exercise caution

when handling such records. We clarify here that while we are not making informal caregivers subject to the final rule requirements to develop formal policies and procedures, we do encourage all lawful holders to protect records. For example, informal caregivers should at least take reasonable steps to protect the confidentiality of patient identifying information.

We are finalizing breach notification requirements for part 2 programs; lawful holders are not subject to breach notification requirements.

De-Identification

Proposed Rule

Section 3221(c) of the CARES Act required the Department to apply the HIPAA standard in 45 CFR 164.514(b) for de-identification of PHI to part 2 for the purpose of disclosing part 2 records for public health purposes. To further advance alignment with HIPAA and reduce burden on disclosing entities, the Department proposed to apply 45 CFR 164.514(b) to the existing de-identification requirements in part 2: §§ 2.16 (Security for records) and 2.52 (Research) (discussed below). Specifically, the Department proposed to modify § 2.16(a)(1)(v) (for paper records) and (a)(2)(iv) (for electronic records), to read as follows: “[r]endering patient identifying information de-identified in accordance with the requirements of the [HIPAA] Privacy Rule at 45 CFR 164.514(b), such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder.”

As proposed, this provision would permit part 2 programs to disclose records de-identified in accordance with the implementation specification in the HIPAA Privacy Rule (*i.e.*, the expert determination method or the safe harbor method) but the provision does not reference the HIPAA Privacy Rule standard at 45 CFR 164.514(a) that the implementation specification is designed to achieve—that the information is de-identified such that there is no reasonable basis to believe that the information disclosed can be used to identify an individual.

Comment

Many commenters expressed support for the Department’s de-identification proposal citing a variety of reasons. One health system, stating that many part 2 programs are embedded within covered entities or share workforces with such programs, commented that de-identification standards within part 2

consistent with the HIPAA Privacy Rule would reduce workforce confusion, inadvertent non-compliance, and unintentional leaks of confidential information. A government agency commented that the express alignment with the HIPAA Privacy Rule was a welcome clarification that would protect the privacy and confidentiality of SUD patients. An individual commented that it would be prudent to enact the standards in 45 CFR 164.514(b) to offer more protection to patients and that doing so would not create adverse consequences. A managed care organization suggested that HIPAA provided an appropriate existing regulatory standard for rendering part 2 records non-identifiable. A few commenters, all health systems that partly specialize in providing SUD services, expressed strong support for the proposal and the principle that programs should not be required to obtain consent from individuals prior to de-identifying their information.

Response

We appreciate these comments.

Comment

Some commenters, including a health IT vendor and a few health information management associations, expressed support for the Department’s proposal but also urged the Department to “fully align” the part 2 de-identification standard with the HIPAA Privacy Rule. For example, one of these commenters opined that the language “such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder” is not the HIPAA de-identification standard, and that the Department should instead use the exact language of HIPAA. Other commenters urged the Department to expressly clarify that both the HIPAA safe harbor method and expert determination method could satisfy the proposed de-identification requirements for part 2 records. A behavioral health advocacy organization asked the Department to clarify that the definition of part 2 “records” does not include de-identified records consistent with the HIPAA Privacy Rule’s treatment of de-identified health information.

Response

We agree that, as drafted, the Department’s proposal does not fully align with the regulatory text of the full de-identification standard in the HIPAA Privacy Rule, which includes paragraphs (a) and (b) of 45 CFR 164.514. We clarify here that by

incorporating the HIPAA standard codified at 45 CFR 164.514(b), either method of de-identification of PHI can be used to de-identify records under part 2. We also note here a critical difference between the definitions of PHI under the HIPAA Privacy Rule and records in this part. The definition of PHI is grounded in the recognition that it is “individually identifiable health information.”¹⁸⁴ The HIPAA Privacy Rule standard for de-identification therefore renders PHI no longer “individually identifiable.” In this part, the definition of records does not refer to “individually identifiable” information, but rather information “relating to a patient” and is already understood to relate to SUD records. The final rule modifies the de-identification standard in § 2.16(a)(1)(v) (for paper records) and (a)(2)(iv) (for electronic records) so it aligns more closely with the HIPAA language such that the de-identified part 2 information cannot be “used to identify a patient.”

Comment

A few HIEs asked the Department to re-examine the “base minimum” standards for de-identified data, opining that some data may be anonymized for some algorithms, but as technology continues to improve, “de-identification in perpetuity” is truly unknown, and therefore the proposed standard may still represent a privacy risk for patients.

Response

The Department acknowledges the concerns about the burgeoning ability of some technologists to re-identify data stored in large data sets. The Department is committed to monitoring these issues as it works to determine their application to the HIPAA and part 2 de-identification standards.

Comment

One commenter, a health system, suggested that the Department make explicit the right to use part 2 records for health care operations to create a de-identified data set without patient consent. Another commenter, a health plan, recommended that the Department remove the requirement to obtain express written consent to create a de-identified data set because it conflicts with the HIPAA Privacy Rule, is counterproductive, and confuses patients when they receive a notice requesting consent to use their SUD data once de-identified.

¹⁸⁴ See 45 CFR 160.103 (definition of “Protected health information”).

Response

We appreciate the comment, but are constrained by the authorizing statute at 42 U.S.C. 290dd–2, which sets forth the circumstances for which records subject to part 2 may be disclosed. Where part 2 programs are not disclosing to a covered entity, the CARES Act amendments did not rescind the requirement to obtain consent prior to disclosing records for TPO.¹⁸⁵

Comment

One commenter, an industry trade association for pharmacies, commented that § 2.16 should simply refer to rendering the patient identifying information de-identified where practicable, and then define “de-identified” in section § 2.11 as data which meets the standard for de-identification under HIPAA.

Response

The proposed regulatory text is consistent with the intent expressed by the commenter, but still comports with the language required by the CARES Act for disclosures for public health activities. We therefore believe that we are finalizing a more workable standard because it is uniform across the regulation.

Comment

Several commenters opposed the proposed de-identification standard for various reasons. A privacy advocacy organization commented that the target HIPAA standard is outdated and needs “tightening.” A few HIE organizations commented that the proposal would materially and detrimentally affect the use of SUD information from part 2 records in limited data sets. These organizations interpreted the current part 2 regulations to only require removal of “direct identifiers” and believed that, under HIPAA, a limited data set can be used and disclosed for research, public health, and health care operations activities if the recipient agrees to a HIPAA data use agreement, which prohibits (among other things) re-identification of individuals. These organizations further suggested that changing §§ 2.16 and 2.52 to require use of the more stringent HIPAA de-identification standard under 45 CFR

¹⁸⁵ The HIPAA term also includes a description of the activities that are excluded as not constituting a breach, and an explanatory paragraph that applies a breach presumption when an “acquisition, access, use, or disclosure” of PHI occurs in a manner not permitted under the HIPAA Privacy Rule, and that fails to demonstrate a low probability of breach based on breach risk assessment. See discussion of proposed definition of the term “breach” above.

164.514(b) will prevent researchers, public health authorities, quality improvement organizations, and others from using a limited data set containing part 2 SUD data. A limited data set is useful for research, public health, and quality improvement activities because it permits analysis of health data in connection with certain identifiers that are relevant to health outcomes, such as age, race, and gender. Prohibiting use of limited data sets for research involving part 2 records may ultimately deny SUD patients the benefits of better and more effective treatments and services. They recommended that the Department continue to consider limited data sets of SUD records as non-patient identifying information under part 2 at least for purposes of research, public health, and health care operations. With respect to consent models for de-identification, these entities requested that it be left up to part 2 programs and other lawful holders of part 2 data to decide—based on their patient populations and business needs—what is the most effective model for their community.

Response

We acknowledge the relatively large number of commenters raising the possibility that the Department codify a limited data set option in this regulation. Because many of these comments were submitted in response to our proposal to incorporate the same de-identification standard proposed here into § 2.52 (Scientific research), our response to the comments on limited data sets and similar comments related to research are addressed together, below.

Comment

One individual commented that the proposal to re-align de-identification with HIPAA lowers the part 2 standard from an objective standard to one that is subjective. The commenter believed that the phrase “no reasonable basis to believe” was subjective and would decrease the researcher’s responsibility. By contrast, under existing § 2.52 requirements information is de-identified “such that the information cannot be re-identified and serve as an unauthorized means to identify a patient” is a more objective standard. Another individual commented that the proposed standard is vague and likely unenforceable.

Response

We disagree with the commenters’ characterization of the proposed change as creating a standard that is subjective or vague and unenforceable. The HIPAA standard incorporated here clearly

identifies two methods for de-identifying records, the expert determination method and the safe harbor method, which set forth specific requirements that are long established and well understood in the health care industry.

Final Rule Related to De-Identification of Records

We agree with commenters who urged the Department to fully align the de-identification standard in this part with the standard in the HIPAA Privacy Rule. Whereas the part 2 requirement protected records identifying a patient as having or having had an SUD, the HIPAA standard at 45 CFR 164.514(a) protects information that identifies or can be used to identify an individual. The existing part 2 standard focuses on protection of a limited number of data points based on one health condition (*i.e.*, SUD) while HIPAA protects the identity of the individual in connection with any health care and thus already incorporates protection of the information in part 2. Because 45 CFR 164.514(a) shields a wider range of data elements from disclosure, it is more protective of privacy than the existing part 2 de-identification requirement. By complying with the HIPAA standard, a part 2 program would also be meeting the requirements of the existing part 2 de-identification standard.

The final rule incorporates the HIPAA Privacy Rule de-identification standard in 45 CFR 164.514(b) into § 2.16 as proposed, and further modifies paragraph (a) of this section to more fully align with the complete HIPAA de-identification standard, including language that is similar to that in the HIPAA Privacy Rule at 45 CFR 164.514(a). To achieve this, we are deleting the existing part 2 phrase “as having or having had a substance use disorder” and retaining the phrase “such that there is no reasonable basis to believe that the information can be used to identify a particular patient.” Section 2.16(a)(1)(v) and (a)(2)(iv) are now modified as § 2.16(a)(1)(i)(E) and (a)(1)(ii)(D) and read as “[r]endering patient identifying information de-identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a particular patient.” We removed the language “the HIPAA Privacy Rule” from in front of the regulatory references to 45 CFR 164.514(b) because we believe it unnecessary and for consistency throughout this final rule.

By adopting the same de-identification standard as we are

required to adopt for public health disclosures (in new § 2.54) into this provision (and in § 2.52 for scientific research purposes, discussed below), we provide a uniform method for de-identifying part 2 records for all purposes and provide more privacy protection than our proposed incorporation of only HIPAA 45 CFR 164.514(b). We also make clear here that the inability to identify an individual, as consistent with the language in 45 CFR 164.514(a) of HIPAA, includes the inability to identify them as a person with SUD. The final rule therefore would include the interpretation that is consistent with our initial proposal, but we believe it also protects from reidentification a broader scope of identifiers. This approach is also most responsive to commenters who generally agreed that the de-identification standards for both HIPAA and part 2 should completely align.

Breach Notification

Overview

Section 290dd–2(j) of 42 U.S.C., as amended by the CARES Act, requires the Department to apply the HIPAA breach notification provisions of the HITECH Act (codified as 42 U.S.C. 17932, Notification in the case of breach) to part 2 records “to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.” Paragraph (k)(1) of 42 U.S.C. 290dd–2 incorporated a definition of the term breach, giving it the same meaning as under the HIPAA regulations. The HIPAA Breach Notification Rule at 45 CFR 164.402 defines breach as “the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.”¹⁸⁶ Paragraph (k)(9) of the 42 U.S.C. 290dd–2 incorporated a definition of “unsecured protected health information,” giving it the same meaning as under the HIPAA regulations. The HIPAA Breach Notification Rule defines “unsecured protected health information” to mean PHI “that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111–5.”

¹⁸⁶ *Id.*

Paragraph (a) of 42 U.S.C. 17932 contains the HIPAA¹⁸⁷ breach notification requirements for covered entities; paragraph (b) requires a business associate of a covered entity to notify the covered entity when there is a breach and includes requirements for the notice; paragraph (c) sets forth the circumstances for when a covered entity or business associate shall treat a breach as discovered; and paragraphs (d) through (g) contain requirements related to timeliness of notice, method of notice, content of notice, and allowance for delay of notice authorized by law enforcement, respectively. Other paragraphs define “unsecured PHI,” set forth requirements for congressional reporting, and authorize interim regulations. The Department implemented 42 U.S.C. 17932 in the HIPAA Breach Notification Rule codified at 45 CFR 164.400 through 164.414.

Proposed Rule

To implement the new requirements in paragraph (j) of 42 U.S.C. 290dd–2, as amended by the CARES Act, the Department proposed to modify the heading of § 2.16 to add “and notification of breaches” and add a new paragraph § 2.16(b) to require part 2 programs to establish and implement policies and procedures for notification of breaches of unsecured part 2 records consistent with the requirements of 42 U.S.C. 17932. The HIPAA Breach Notification Rule refers to “unsecured protected health information.” The existing part 2 regulation does not have a definition of “unsecured records” but to align with HIPAA we proposed such a definition, as discussed in § 2.11, above.

Comment

The commenters who addressed the breach notification proposals unanimously expressed support for applying breach notification requirements to part 2, with slightly more than half expressing general support without further elaboration. Other supportive commenters expressed additional views, including that the Department’s proposal: implemented the CARES Act; was likely to ensure patient confidentiality in the same manner as HIPAA; and could provide a “counterweight” to the perceived lessening of part 2 protections brought about by the CARES Act.

¹⁸⁷ The HIPAA Breach Notification Rule, codified at 45 CFR parts 160 and 164, subparts A and D, implements sec. 13402 of the HITECH Act (codified at 42 U.S.C. 17932).

Response

The Department appreciates these comments.

Comment

Almost half of all commenters on breach notification expressed support for the proposal but requested clarification or guidance, especially related to the interaction of newly proposed breach notification requirements and HIPAA breach notification requirements. For example, one commenter, a health plan association, recommended that the Department clarify that if a use or disclosure of part 2 records is permitted by the HIPAA Privacy Rule, then the same use or disclosure would not be considered a breach under part 2. This same commenter requested, in the alternative, that if the activity did amount to a breach under part 2, the rule should provide that states have the ability to exempt HIPAA covered entities and business associates from part 2 breach notification requirements to avoid overlap, confusion, or conflict among individuals who receive notification. A legal advocacy association commented that HHS should clarify that the breach notification requirement applies to disclosures that violate the part 2 standard of confidentiality, and not just disclosures that violate the HIPAA Privacy Rule, and that the Department should amend the definition of “breach” in § 2.11 or clarify in § 2.16 that patients should be notified of any acquisition, access, use, or disclosure of part 2 records in a manner not permitted under 42 CFR part 2. Yet another commenter, a health system, requested clarification of whether overlapping breach reporting obligations triggered by an activity that violated both HIPAA and part 2 would involve communicating with OCR, SAMHSA, or both.

Response

In the CARES Act, Congress replaced the criminal penalties for part 2 violations with the HITECH civil penalty structure that is applied to violations of the HIPAA regulations, as well as criminal penalties for certain violations. The CARES Act did not include an exemption for persons who are subject to both regulatory schemes, and who commit acts that violate both regulatory schemes. We expect a new enforcement process to ensure efficient use of Department agencies’ resources, emphasize bringing entities into compliance with part 2, and avoid

duplicative reporting by part 2 programs.

Comment

We received several comments related to breach notification and the impact of the proposed effective dates and compliance dates for a final rule. A hospital association and a health IT vendor recommended that the Department phase in the breach notification requirements or extend the period of time for compliance beyond the proposed timeline, noting that compliance with part 2 is already complex and a potential deterrent to treating patients with SUD, and that the risk of monetary penalties would further deter providers from taking on these patients. One of these commenters also noted that implementing breach notification capability could be a time-consuming process requiring time beyond what the Department estimated. Several commenters stated that many part 2 programs are also subject to HIPAA and thus are already complying with breach notification, so the proposal would not create any additional burden for such programs. One commenter believed that the number of entities or individuals affected by the proposal (part 2 programs not subject to HIPAA) would be small.

Response

We appreciate the concerns expressed about the potential complexity of implementing breach notification among this community of providers but agree that many providers have already implemented breach notification because they are also covered entities under HIPAA and that overall, a relatively small number of entities will be affected. We are mindful, however, that this regulation must also still serve the community of part 2 programs that are not subject to HIPAA. We remind such entities that the required compliance date would not occur until almost two years after the rule becomes effective. These entities may wish to review existing guidance on breach notification.¹⁸⁸

Comment

One anonymous commenter urged the Department to cease or disallow part 2 programs, covered entities, and investigative agencies from relying on TV and newspaper notification avenues because these methods are no longer likely to be seen by patients, and

¹⁸⁸ See, e.g., U.S. Dep’t of Health and Human Servs., “Breach Notification Rule” (July 2013), <https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html>.

therefore should not be treated as meaningful or considered cost effective.

Response

We note at the outset that we have not proposed to make breach notification applicable to lawful holders such as “investigative agencies.” We agree that breach notification provisions across types of entities should be uniform. We also believe the commenter’s suggestion is reasonable; however, we believe that more breach notification options, rather than fewer options, are preferable.

Final Rule

The Department adopts the proposal to add paragraph (b) to § 2.16 to require part 2 programs to establish and implement policies and procedures for notification of breaches of unsecured part 2 records consistent with the requirements of 45 CFR parts 160 and 164, subpart D. First, we believe this provision is consistent with the CARES Act requirement to apply breach notification to part 2 in the same manner as it applies to covered entities for breaches of unsecured PHI. Second, we believe the same public policy objectives of the HIPAA Breach Notification Rule as applied to covered entities are furthered by establishing analogous requirements for part 2 programs. In the NPRM we established those policy objectives as: (1) greater accountability for part 2 programs through requirements to maintain written policies and procedures to address breaches and document actions taken in response to a breach; (2) enhanced oversight and public awareness through notification of the Secretary, affected patients, and in some cases the media; (3) greater protection of patients through obligations to mitigate harm to affected patients resulting from a breach; and (4) improved measures to prevent future breaches as part 2 programs timely resolve the causes of record breaches.

Finally, as we discuss in greater detail in Definitions, in § 2.11 above, we are finalizing proposed definitions for “breach” and “unsecured records.” In addition to the term “breach” being required by the amended statute, we believe incorporating these terms and definitions, as proposed, helps bring clarity to regulated entities on how to operationalize breach notification requirements aligned with HIPAA in part 2. In keeping with these changes, we are finalizing the proposed modification of the heading of § 2.16 so that it now reads “Security for records and notification of breaches.”

Section 2.17—Undercover Agents and Informants

As we discussed above, the final rule adopts the proposed addition of the language “or disclosed” behind “used” in this section so that the use and disclosure of part 2 records is prohibited by this section pursuant to the statutory authority. We did not receive public comments on this proposal and there are no other substantive changes to this section.

Section 2.19—Disposition of Records by Discontinued Programs

Proposed Rule

Section 2.19 requires a part 2 program to remove patient identifying information or destroy the records when a program discontinues services or is acquired by another program, unless patient consent is obtained or another law requires retention of the records. The Department proposed to create a third exception to this general requirement to clarify that these provisions do not apply to transfers, retrocessions, and reassumptions of part 2 programs pursuant to the ISDEAA, to facilitate the responsibilities set forth in 25 U.S.C. 5321(a)(1), 25 U.S.C. 5384(a), 25 U.S.C. 5324(e), 25 U.S.C. 5330, 25 U.S.C. 5386(f), 25 U.S.C. 5384(d), and the implementing ISDEAA regulations.¹⁸⁹ The Department also proposed wording changes to improve readability and modernize the regulation, such as by referring to “non-electronic” records instead of “paper” records, and structural changes to the numbering of paragraphs.

Comment

One commenter asserted that the Department’s proposed exception to clarify that these provisions do not apply to transfers, retrocessions, and reassumptions of part 2 programs pursuant to the ISDEAA is a logical addition that will promote continuity of patient treatment. However, the commenter requested further clarification of the rule’s record retention requirements for discontinued or acquired programs, including the provision that requires labeling stored non-electronic record with specific regulatory language. The commenter asked if the reference in the NPRM preamble to “another law” that might require record retention was a reference to HIPAA for covered entities.

¹⁸⁹ For further information on the ISDEAA, see Indian Health Service, Title 1, HHS, <https://www.ihs.gov/odsct/title1/>.

Response

The Department appreciates the comments about clarifying in the final rule that these provisions do not apply to transfers, retrocessions, and reassumptions of part 2 programs pursuant to the ISDEAA. Part 2 has long had requirements pertaining to paper records which were updated in 2017 to apply to electronic records of discontinued programs as well.¹⁹⁰

When there is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the part 2 program, the dates of record retention would be reflected in the requirements of that law under § 2.19(a)(2). The NPRM discussion of this was not intended as a reference to a specific law, but more generally to records retention laws which are typically established in state law for medical records. The HIPAA regulations do not address the time period for retention of medical records, but contain requirements for how retained records must be safeguarded. The HIPAA regulations also address retention of compliance documentation that may be located within a medical record (such as a signed authorization) or stored separately (such as security risk analyses). HIPAA Security Rule requirements for proper storage and security of records also may apply to records maintained by part 2 programs that also are covered entities.¹⁹¹

Comment

Another commenter expressed concern that current EHR systems do not support removing only part 2 data from one program for a particular patient or subset of patients, so it may not be technically feasible to remove patient identifying information or destroy the data as required by § 2.19. The commenter claimed that the requirements for this section as described in the NPRM would require EHRs to be redesigned and therefore recommends alignment with the HIPAA Privacy and Security Rules. The commenter asserted that the HIPAA Security Rule requires that covered

¹⁹⁰ 82 FR 6052, 6076; 81 FR 6987, 6999 (Feb. 9, 2016).

¹⁹¹ See, e.g., U.S. Dep’t of Health and Human Servs., “Security Rule Guidance Material” (June 29, 2023), <https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html>. See also, “Guidance on Risk Analysis,” *supra* note 115; U.S. Dep’t of Health and Human Servs., “Does the HIPAA Privacy Rule require covered entities to keep patients’ medical records for any period of time?” (Feb. 18, 2009), <https://www.hhs.gov/hipaa/for-professionals/faq/580/does-hipaa-require-covered-entities-to-keep-medical-records-for-any-period/index.html>.

entities implement policies and procedures that address the final disposition of ePHI and/or the hardware or electronic media on which it is stored, as well as to implement procedures for removal of ePHI from electronic media before the media are made available for re-use.

Response

We appreciate the feedback. Distinct requirements for disposition of part 2 records for discontinued programs have existed since 1987.¹⁹² In 2017 the Department applied this section to electronic records.¹⁹³ At that time, we cited resources that may support compliance with this requirement including from OCR (e.g., *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*) and the National Institute of Standards and Technology (NIST) (e.g., *Special Publication 800–88, Guidelines for Media Sanitization*).¹⁹⁴ These and other resources developed by OCR, NIST, ONC, and others can continue to aid compliance with this section. The Department also notes that part 2 has established distinct requirements in § 2.19 for disposition of part 2 records that may be more stringent and specific than those articulated in the HIPAA Security Rule based on the purposes of part 2 and stigma and discrimination associated with improper disclosure of SUD records. This section was updated in the 2020 final rule to apply to use of personal devices and accounts.¹⁹⁵

Final Rule

The Department is finalizing all proposed changes to this section without further modification.

Section 2.20—Relationship to State laws

Proposed Rule

Section 2.20 establishes the relationship of state laws to part 2 and provides that part 2 does not preempt the field of law which it covers to the exclusion of all applicable state laws, but that no state law may either authorize or compel a disclosure prohibited by part 2. Part 2 records frequently are also subject to regulation by various state laws. For example, similar to part 2, state laws impose restrictions to varying degree on uses and disclosures of records related to

¹⁹² See 52 FR 21796.

¹⁹³ 82 FR 6052, 6076.

¹⁹⁴ 82 FR 6052, 6075; 81 FR 6987, 6999.

¹⁹⁵ 85 FR 42986, 42988.

SUD¹⁹⁶ and other sensitive health information, such as reproductive health, HIV, or mental illness.¹⁹⁷ The Department stated in the NPRM its assumption that, to the extent state laws address SUD records, part 2 programs generally are able to comply with part 2 and state law. The Department requested comment on this assumption and further requested examples of any circumstances in which a state law compels a use or disclosure that is prohibited by part 2, such that part 2 preempts such state law.

Comment

Several commenters asserted that complete Federal preemption is needed on part 2 issues with respect to state law, or barriers to care coordination will continue to exist. One commenter, a county government, said that part 2 preemption of state law is a problem in California because it creates a barrier when parents attempt to obtain SUD treatment for their minor children over the objection of the minor. Part 2 prevents disclosure of the minor's records without the minor's consent. Another commenter believed that part 2 conflicts with state law regarding state-mandated reporting on other types of abuse other than child abuse (such as elder abuse or domestic violence) and creates a dilemma for part 2 providers who need to report because there is not a "required by law" exception within part 2.

Response

We acknowledge that considerable variation in patient consent laws exists for minors at the state level and discuss these issues in more detail in responding to comments regarding § 2.14.¹⁹⁸ The Department also notes that state behavioral health privacy laws may vary.¹⁹⁹

¹⁹⁶ See, e.g., Mich. Comp. Laws sec. 333.6111 (expressly excluding SUD records from an emergency medical service as restricted); and NJ Rev. Stat. sec. 26:2B–20 (2013) (requiring records to be confidential except by proper judicial order whether connected to pending judicial proceedings or otherwise).

¹⁹⁷ See, e.g., MO Rev. Stat. sec. 191.731 (requiring SUD records of certain pregnant women remain confidential). Ctrs. for Disease Control and Prevention, "State Laws that address High-Impact HIV Prevention Efforts" (March 17, 2022), <https://www.cdc.gov/hiv/policies/law/states/index.html>; "TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations," *supra* note 122.

¹⁹⁸ See "State-by-State Variability in Adolescent Privacy Laws," *supra* note 172.

¹⁹⁹ See "TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations," *supra* note 122.

With respect to reporting abuse and neglect, 42 U.S.C. 290dd–2 expressly states that the prohibitions of part 2 "do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities." However, no similar references are made to domestic violence, elder abuse, animal abuse, or other similar activities. Moreover, such changes were not proposed in the NPRM. Part 2 does, however, permit reporting a crime on the premises or against part 2 program personnel (§ 2.12(c)(5)), or applying for a court order to disclose confidential communications about an existing threat to life or serious bodily injury (§ 2.62). The Department also advised in the 2017 rule that "if a program determines it is important to report elder abuse, disabled person abuse, or a threat to someone's health or safety, or if the laws in a program's state require such reporting, the program must make the report anonymously, or in a way that does not disclose that the person making the threat is a patient in the program or has a substance use disorder."²⁰⁰ A program could file a report therefore in such a way that does not note that the subject of the report is a patient in a part 2 program or has an SUD.

Comment

One commenter supported balancing the alignment of Federal privacy law and regulations with HIPAA and applicable state law for the purposes of TPO. Another commenter believed that to foster care coordination the Department should work with states to better align with the Federal standards to improve care coordination and individual patient outcomes.

Response

We appreciate the comments on our proposed changes to align part 2 with HIPAA consistent with the CARES Act.

Comment

A state agency requested express permission within the regulation to permit disclosures to state data collection agencies, such as APCDs, because there is not a "required by law" provision in this part that would otherwise permit SUD records to be submitted to the state agencies that collect other health and claims data. A state agency requested that the final rule clearly authorize state agencies that maintain repositories of health care claims and discharge data to receive SUD information under 42 CFR part 2.

²⁰⁰ 82 FR 6052, 6071.

SAMHSA, the commenter said, addressed a similar issue with state-operated PDMPs by clarifying in its 2020 final rule that such disclosures were authorized under 42 CFR part 2. The commenter reported that the PDMP modification strengthened a critical component of states' ability to monitor access, use, and abuse of prescription drugs, while protecting patient privacy and confidentiality.

Response

We appreciate the comment and recommendation. The Department, in 2020, added a new section § 2.36 (Disclosures to prescription drug monitoring programs),²⁰¹ based on a regulatory proposal. No provision was proposed in the NPRM pertaining to APCDs/multi-payer claims databases (MPCDs) and thus there is no basis to add such a provision in the final rule. The Department previously declined to include exceptions to various requirements for APCDs/MPCDs after consideration of comments received on these issues in 2017.²⁰²

Comment

A state agency said that in its state, the majority of SUD treatment records are covered by part 2; it has communicated to licensed SUD treatment providers that they will not be cited for state regulatory violations if they disclose information as permitted by part 2. Licensed providers who are not part 2 programs are currently asked to verify this status with the state if a disclosure is made under HIPAA that would not be permitted by part 2.

Response

The Department appreciates this information in response to our request for input about these issues.

Comment

For one commenter, the final rule provides an opportunity to encourage states to update regulations that can often be outdated and confusing with regard to applicability. Such updates could facilitate care coordination and access. A hospital association requested more guidance on the interaction of Federal and state laws and that hospitals in states with confidentiality laws specific to SUD or citing part 2 will have to invest significant time and financial resources into understanding the interaction between Federal and state laws and how to incorporate those laws into real-time care decisions. Some hospitals also may provide services in

²⁰¹ See 85 FR 42986, 43015; 84 FR 44568, 44576.

²⁰² 82 FR 6052, 6079.

multiple states, the commenter pointed out, and patients may therefore receive treatment at facilities in more than one state. Other commenters requested additional guidance on the interaction between Federal and state SUD confidentiality requirements and provide technical assistance to help providers operationalize these requirements. One commenter also requested guidance to address such issues as hospitals providing services in multiple states and application of state laws to out-of-state telehealth consultations.

Response

We appreciate these comments and may provide additional guidance and technical support to states and others after this rule is finalized. As previously noted, the Department supports the Center of Excellence for Protected Health Information Related to Behavioral Health, that can provide guidance and technical support on behavioral health privacy laws.²⁰³ The Department will continue to support this Center. The Department supports efforts to facilitate telehealth use consistent with HIPAA, part 2, and other state and Federal requirements. The Department has developed and supported resources to promote appropriate use of telehealth for SUD and other behavioral health conditions.²⁰⁴ The Department acknowledges that hospitals or other providers providing services in multiple states may face more complex compliance burdens and may need to consult legal counsel to ensure compliance, as the Department has previously advised.²⁰⁵

Comment

One commenter said that any changes need to take into account discrepancies between state and Federal laws regarding release of information and ways to protect patients from the consequences of their information being used against them.

Response

The Department acknowledges that the complex intersection of state and

Federal behavioral health privacy statutes and regulations may result in unnecessary or improper disclosures. As we have noted in this section, part 2 does not preempt more stringent state statutes or regulations. Likewise, we have stated that HIPAA constitutes a floor of privacy protection that does not preclude more stringent state laws.²⁰⁶

Comment

One commenter was concerned that Federal efforts to promote interoperability may intersect with conflicting state requirements, pointing to the Federal Trusted Exchange Framework and Common Agreement (TEFCA) initiative as an example.²⁰⁷ The commenter believed that the health care industry does not yet fully understand all the potential conflicts and how they will impact health information exchange. Another commenter suggested requiring electronic records to display the basis when certain information is not visible or accessible (e.g., due to state law, patient restriction, etc.).

Response

The Department will continue to support health IT and behavioral health integration by ensuring that TEFCA and other efforts are consistent with part 2 and take into account state requirements.²⁰⁸ As noted above, the Department has developed guidance for part 2 programs on exchanging part 2 data and may update such guidance in the future.²⁰⁹ The Department continues to support EHRs and health IT compliant with part 2 and HIPAA requirements as well as care coordination and behavioral health integration.²¹⁰

²⁰⁶ See U.S. Dep't of Health and Human Servs., "Preemption of State Law," <https://www.hhs.gov/hipaa/for-professionals/faq/preemption-of-state-law/index.html>. For surveys of state privacy laws and discussion of state requirements see, e.g., "50-State Survey of Health Care Information Privacy Laws," *supra* note 107; George Washington Univ.'s Hirsh Health Law and Pol'y Program and the Robert Wood Johnson Found., "States," Health Information & the Law, <http://www.healthinfolaw.org/state/>; "TAC Assessment Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations," *supra* note 122.

²⁰⁷ See The Off. of the Nat'l Coordinator for Health Info. Tech. (ONC), "Trusted Exchange Framework and Common Agreement (TEFCA)," <https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca>.

²⁰⁸ See "Behavioral Health," *supra* note 133.

²⁰⁹ See "Substance Abuse Confidentiality Regulations," *supra* note 113.

²¹⁰ See "Behavioral Health," *supra* note 133.

Comment

A commenter recommended that a Federal electronic consent standard should override conflicting state law.

Response

While electronic signatures are beyond the scope of this rulemaking and no modifications to electronic signature requirements were proposed by the Department, both HIPAA and part 2 permit electronic signatures for authorizations or consents consistent with state law. As stated in HHS guidance, the HIPAA Privacy Rule "allows HIPAA authorizations to be obtained electronically from individuals, provided any electronic signature is valid under applicable law."²¹¹ The Department also has stated in guidance and regulation that under part 2 electronic signatures are permissible.²¹² In 2017 the Department revised § 2.31 to "to permit electronic signatures to the extent that they are not prohibited by any applicable law." However, the Department also advised that "[b]ecause there is no single federal law on electronic signatures and there may be variation in state laws, SAMHSA recommends that stakeholders consult their attorneys to ensure they are in compliance with all applicable laws."²¹³

The requirements for providing consent under § 2.31 and the notice and copy of consent to accompany disclosure under § 2.32 could be met in electronic form. The requirements of § 2.32 would not require the written consent, copies of a written consent, or a notice to accompany a disclosure of part 2 records to be in paper or other hard copy form, provided that any required signatures obtained in electronic form would be valid under applicable law. This interpretation is consistent with the Department's approach under the HIPAA Privacy Rule. OCR has provided prior guidance stating that covered entities can disclose PHI pursuant to an electronic copy of a valid and signed authorization, and the

²¹¹ U.S. Dep't of Health and Human Servs., Off. for Civil Rights, "How do HIPAA authorizations apply to an electronic health information exchange environment?" (Sept. 17, 2021), <https://www.hhs.gov/hipaa/for-professionals/faq/554/how-do-hipaa-authorizations-apply-to-electronic-health-information/index.html>; U.S. Dep't of Health and Human Servs., "Does the Security Rule require the use of an electronic or digital signature?" (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/faq/2009/does-the-security-rule-require-the-use-of-an-electronic-signature/index.html>.

²¹² See "Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)," *supra* note 150.

²¹³ 82 FR 6052, 6080.

²⁰³ See "About COE PHI," *supra* note 105.

²⁰⁴ See The Ctr. of Excellence for Protected Health Info., "Telehealth," <https://coephi.org/protecting-health-information/telehealth-resources/>; U.S. Dep't of Health and Human Servs., "Telehealth for behavioral health care," <https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-behavioral-health/>; Substance Abuse and Mental Health Servs. Admin., "Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders" (2021), <https://www.samhsa.gov/resource/ebp/telehealth-treatment-serious-mental-illness-substance-use-disorders>.

²⁰⁵ 82 FR 6052, 6071.

Privacy Rule allows HIPAA authorizations to be obtained electronically from individuals, provided that any electronic signature is valid under applicable law.²¹⁴

Final Rule

After considering the public comments on the relationship of part 2 to state laws we are finalizing this section as proposed without further modification.

Section 2.21—Relationship to Federal Statutes Protecting Research Subjects Against Compulsory Disclosure of Their Identity

The Department adopts the proposal in § 2.21(b) to reorder “disclosure and use” to read “use and disclosure” to better align the wording of this section with language used in the HIPAA Privacy Rule. A provider health system supported the proposal and no other comments were received on this proposal.

Section 2.22—Notice to Patients of Federal Confidentiality Requirements²¹⁵

Patient Notice Proposed Rule

Section 3221(i) of the CARES Act required the Secretary to update the HIPAA NPP requirements at 45 CFR 164.520 to specify new requirements for covered entities and part 2 programs with respect to part 2 records that are PHI (*i.e.*, records of SUD treatment by a part 2 program that are transmitted or maintained by or for covered entities). By applying such requirements, entities that are dually regulated by both part 2 and HIPAA would be subject to the notice requirements. Discussed here and consistent with our approach throughout this rulemaking, in addition to proposing the required updates to 45 CFR 164.520 (discussed below), we also proposed to revise the Patient Notice at § 2.22.

As explained in the NPRM, to the extent the HIPAA regulations and part 2 cover different, but often overlapping,

sets of regulated entities, and the HIPAA NPP offers more robust notice requirements than the Patient Notice, the Department proposed to modify § 2.22 to provide the same information to patients of part 2 programs as individuals receive under the HIPAA Privacy Rule. The Department’s proposed modifications to the Patient Notice would also restructure it to substantially mirror the structure of the HIPAA NPP but exclude those elements that are inapplicable to part 2 programs. The specific proposed changes are described in detail in the NPRM and set forth below following the discussion of general comments.

Overview of Comments

The Department received more comments about its approach to modifying the Patient Notice to align with the HIPAA NPP than comments about specific elements of the proposed notice. Some commenters supported aligning part 2 Patient Notice requirements with the HIPAA NPP. Other commenters expressed concerns, asked for clarity on certain specific proposed requirements, or urged the Department to provide resources or examples to support compliance.

Response

We appreciate the comments about the proposed changes and discuss our response to specific concerns expressed by commenters below.

Patient Understanding Comment

Some commenters questioned whether the Patient Notice would ensure part 2 patients, programs, and recipients of part 2 records understand how part 2 records will be used, disclosed, and protected. Such requirements, these commenters said, should be delineated in easy-to-understand wording in the patient’s primary language. One commenter, describing their experiences as a patient and professional, said that they were not educated about the consent forms or what they were disclosing and their rights.

Some commenters expressed concern that patients may not understand the revised notices, suggesting that the Department’s approach could lead to additional downstream disclosures and legal consequences for patients even as it supported care coordination. A medical professionals association also emphasized its view that the Department should ensure standard and easily understandable notices of privacy practices. Other commenters suggested the Patient Notices be simplified and

streamlined such as limiting notices to one page or gearing notices to a fifth-grade reading level. A state agency suggested that the Patient Notice adhere to language and disability access standards to the extent required under HIPAA. A privacy association opined that the proposed rule allows a patient to consent to a broad range of TPO disclosures, but also notes that SUD patients may at times lack capacity to understand the Patient Notice. These challenges may also apply to understanding consents and to managing revocation of consents. However, the association believes that this result is dictated by the statute rather than the Department’s approach in the NPRM. A county government also expressed its view that it is difficult to provide these notices when the patient is undergoing detoxification or treatment for a SUD.

Response

We appreciate these comments. We mirrored required elements of the HIPAA NPP in the Patient Notice because we believe that patients have become familiar with it and to reflect the closer alignment between part 2 and HIPAA in the final rule. We have provided further clarification concerning the substantive alignment of part 2 and HIPAA requirements through responses to public comments in several other sections of the final rule. The Department recognizes that outreach and further guidance will be needed both to persons with SUD and to providers in connection with the final rule. The Department will continue to monitor the response to part 2 in the SUD treatment community and will provide clarification of the final rule as needed. We discuss patients who lack capacity to make health care decisions in § 2.15 above.

Single or Streamlined Form Comment

Commenters expressed different views as to whether they preferred using a single document or separate HIPAA and part 2 notices to provide notice statements to patients to aid compliance and patient understanding. One public health agency asked HHS to confirm that a single notice of privacy practices can fulfill both part 2 and HIPAA obligations. Some commenters said that for them that a single notice of privacy practices would reduce burdens or be the most effective way to convey privacy information to patients without creating unnecessary confusion and burden through excessive paperwork and asked for confirmation this was

²¹⁴ U.S. Dep’t of Health and Human Servs., Off. For Civil Rights, “How do HIPAA authorizations apply to an electronic health information exchange environment?” <https://www.hhs.gov/hipaa/for-professionals/faq/554/how-do-hipaa-authorizations-apply-to-electronic-health-information/index.html>.

²¹⁵ In the NPRM, we included a detailed discussion of proposed modifications to HIPAA Privacy Rule 45 CFR 164.520, Notice of privacy practices for protected health information, in addition to modifications proposed to § 2.22, Notice to Patients of Federal Confidentiality. Here, we include a brief explanation that HIPAA Privacy Rule proposed modifications and public comments will be considered in a separate rulemaking.

permitted. An academic health center supported covered entities which have part 2 programs using one NPP addressing key elements of the HIPAA NPP such as a Header, Uses and Disclosures, Individual Rights. If a joint notice is acceptable, a commenter asked that proposed 42 CFR 2.22(b)(1)(i) be updated to note that the 45 CFR 164.520(b)(1)(v)(C) header may be used in a combined notice. A trade association and health plan supported part 2 notices including elements of the HIPAA NPP such as a description of the permitted uses and disclosures of part 2 records, the complaint process, and the patient's right to revoke their consent for the part 2 program to disclose records in certain circumstances.

Response

We have stated both in HIPAA and part 2 guidance that notices for different purposes may be separate or joint/combined so long as the required elements are included.²¹⁶ Thus, either using separate HIPAA, state law, or part 2 notices or combining these notices into one form would be acceptable so long as all required elements are included.

Comment

Commenters also urged the Department to support a simplified or streamlined Patient Notice. One advocacy organization characterized the proposed notice as unwieldy and overly detailed for both patients seeking to understand their rights and covered entities. The Department should streamline both notices and develop model Patient Notices as it has done for HIPAA NPPs. A health plan encouraged the Department to align with the HIPAA Privacy Rule by developing two versions of the part 2 model notice language: (a) the minimum necessary additional language/verbiage, which would be required to be added to an existing HIPAA NPP for entities which already are subject to that requirement; and (b) a notice similar to what is in the proposed rule for entities which do not already have a notice.

Other commenters urged the Department to develop notice templates or model forms in multiple languages. A state agency supported the HIPAA NPP's being translated, at a minimum, into the top three languages for a provider's client population. One

commenter asked the Department to develop at least two example Patient Notices—one directed at providers, and the other directed at payers and health coverage issuers. Another commenter suggested that model Patient Notices were needed for a HIPAA covered entity that has an existing HIPAA NPP and therefore HHS should create a minimal addendum or template which highlights any additional language specifically required to be added to that existing HIPAA NPP relative to this rule. The commenter also urged the Department to develop a Patient Notice template for third-party payers or other entities which may not already use a HIPAA NPP. Commenters urged that given the HIPAA enforcement proposal, there should be a safe harbor for using these standard notices.

Response

We appreciate this comment and understand the value of having a sample or model notice that incorporated the changes finalized in this rule. The Department may, at a future time, develop sample templates and forms to support compliance with § 2.22. We also note that this final rule provides 24 months from the date of publication for compliance with its provisions.

Administrative Burdens

Comment

The Department received several comments stating that proposed changes to the part 2 notice would either reduce or increase part 2 program, provider, or covered entity burdens. While part 2 programs and covered entities would need to update both the Patient Notice and the HIPAA NPP, the benefits outweighed the burdens, according to some commenters. One commenter asked HHS to clarify that § 2.22 only applies to part 2 programs that are not subject to HIPAA. Another commenter said that as a dually regulated entity it believed that aligning these two notices will reduce dually regulated entities' burden of compliance, and improve patient understanding by reducing the amount of reading required. The commenter said updating notices concurrently would reduce their burden. Many commenters said examples of the updated HIPAA NPP and Patient Notice would be helpful and reduce their administrative burdens. Others also suggested the Department reduce administrative burdens and improve compliance by providing educational resources and templates to providers and patients and work with advocacy organizations to ensure the

notice requirements are understood by patients and practical for providers.

Another commenter supported the proposed changes, stating that it anticipated an additional administrative burden on part 2 programs which are not covered by HIPAA but limited impact or additional burden on those part 2 programs covered by HIPAA. One commenter similarly described what it viewed as potential burdens but said that for entities which are both part 2 programs and covered entities, a portion of the burden would be offset by the ability to have consistent policies and procedures given the new alignment between the part 2 rules and the HIPAA regulations. A medical professionals association, while supporting alignment of the part 2 notice with the HIPAA NPP, suggested there would be an additional burden that modifying the HIPAA NPP for physician practices, especially small practices and those in rural areas.

Response

The Department detailed its analysis of potential costs and benefits in the NPRM and in the RIA below. As we earlier noted, we are finalizing the part 2 Rule only at this time. The Department intends to publish the CARES Act required revisions to the HIPAA NPP provision (45 CFR 164.520) as part of a future HIPAA rulemaking. Thus, this final rule focuses only on changes to the Patient Notice under § 2.22. We intend to align compliance dates for any required changes to the HIPAA NPP and part 2 Patient Notice to enable covered entities to make such changes at the same time.

After both this rule and the forthcoming HIPAA Privacy Rule changes are finalized, while entities initially may require time to update the content of the Patient Notice and HIPAA NPP, commenters stated many part 2 programs, such as those that also are covered entities, may be able to save time and patients may benefit from enhanced protections offered by the revised notices. The Department acknowledges that some smaller, rural, or other types of practices may face increased burdens relative to larger entities, though this may not be true in all cases as many smaller practices or providers may also have familiarity both with HIPAA and part 2. After this rule is finalized, the Department may develop template/model forms or other guidance subsequent to finalizing this rule.

²¹⁶ See U.S. Dep't of Health and Human Servs., "Notice of Privacy Practices for Protected Health Information" (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html>; "Substance Abuse Confidentiality Regulations," *supra* note 113.

Notifying Patients

Comment

Some commenters expressed concerns about notifying patients of new or updated notices. A medical professionals association expressed concern that the notification process as described in the NPRM may be problematic for those patients who lack mailing addresses and substitute notice by publication still might not be sufficient to inform patients about release of their records.

Response

We appreciate the comments and acknowledge that updating the Patient Notice will create some burden for part 2 programs, as may copying and mailing costs; however, we believe that the burdens will be balanced by the overall burden reduction as a result of the decreased number of consents that are required for routine uses and disclosures. Section 2.22 as revised in this rule requires part 2 programs to notify patients when requirements that pertain to a patient's treatment have materially changed. It specifically requires the updated Patient Notice to be provided by the first day the health care is provided to the patient after the compliance date for the program, or for emergency treatment as soon as reasonably practicable after the emergency. The Department's stated intention to hold in abeyance updates to the HIPAA NPP pending a future rulemaking does not negate the Department's expectation that part 2 programs will comply with the requirements in § 2.22. However, as explained above, we intend to align compliance dates for any required changes to the HIPAA NPP and part 2 Patient Notice to enable covered entities to make such changes at the same time.

Recommendations To Change the Proposal

Comment

One commenter noted that the proposed Patient Notice did not include notice that patients could obtain copies of their records at limited costs or in some case, free of charge. The commenter stated that, although §§ 2.22 and 2.23 do not require a part 2 program to give a patient the right to inspect or get copies of their records, but the Department should use the general regulatory authority of the CARES Act (section 3221(i)(1)) to require part 2 programs to allow patients to inspect or get copies of their records. This commenter supported the Patient Notice statement describing the duties of part 2 programs with respect to part 2

records even though it is not required by 42 U.S.C. 290dd–2.

Response

The commenter is correct that these regulations do not create a patient right of access to their records analogous to the HIPAA Privacy Rule right of access.²¹⁷ We discuss patient access and restrictions on use and disclosure in § 2.23.

Comment

A commenter requested modification of the section of the notice pertaining to complaints so that complaints may be filed “either to the Part 2 Program or the Secretary” rather than to the program and the Secretary. Requiring the patient to complain to both entities may intimidate the patient especially if they are dependent on the part 2 program for employment, child welfare, or criminal justice purposes, the commenter asserted.

Response

As we state in § 2.4 (Complaints of noncompliance), a person may file a complaint with the Secretary for a violation of this part by a part 2 program, covered entity, business associate, qualified service organization, or other lawful holder but is not compelled to file a complaint of violation both with the Secretary and the part 2 program. This “no wrong door” approach mirrors the language in the HIPAA NPP for the HIPAA Privacy Rule, and OCR has continued to receive thousands of privacy complaints annually. A patient who files a complaint with a provider may or may not receive a response, and we do not believe a patient should be required to wait before bringing their complaints of noncompliance to the Department's attention. Further, many complaints filed with the Department are readily resolved through voluntary compliance and technical assistance to aid the entity's compliance with the regulation. Thus, we do not believe it will overly burden part 2 programs to allow patients to file complaints directly with the Department.

Final Rule

Header

The Department proposed to require a header for the Patient Notice that would be nearly identical to the header required in the HIPAA NPP (and as proposed for amendment in the NPRM) at 45 CFR 164.520(b)(1)(i) except where

necessary to distinguish components of the notice not applicable to 42 CFR part 2. For example, the Patient Notice that would be provided pursuant to this part would not include notice that patients could exercise the right to get copies of records at limited costs or, in some cases, free of charge, nor would it provide notice that patients could inspect or get copies of records under HIPAA.

The final rule adopts the header as proposed without modification.

Uses and Disclosures

The Department is finalizing its proposal, without modification, to require a part 2 program to include in its Patient Notice descriptions of uses and disclosures that are permitted for TPO, are permitted without written consent, or will only be made with written consent. The Department is finalizing its proposed requirement that a covered entity that creates or maintains part 2 records include sufficient detail in its Patient Notice to place the patient on notice of the uses and disclosures that are permitted or required. Although, as stated in the NPRM, the Department believes section 3221(k)(4) of the CARES Act—stating that certain de-identification and fundraising activities should be excluded from the definition of health care operations—has no legal effect as a Sense of Congress, the Department will finalize its proposed new paragraph (b)(1)(iii) in § 2.22. This provision requires that a part 2 program provide notice to patients that the program may use and disclose part 2 records to fundraise for the program's own behalf only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications. This new notice requirement is consistent with the requirement at § 2.31(a)(5)(iii) in which a part 2 program, when obtaining a patient's TPO consent, must provide the patient the opportunity to elect not to receive fundraising communications.

Rather than referring to “the HIPAA Privacy Rule” we instead refer in this rule to “HIPAA regulations” to describe the redisclosure permission applicable to part 2 programs, covered entities, and business associates following an initial disclosure based on a TPO consent. We believe this modification to what we initially proposed is consistent with our incorporation of the new defined term “HIPAA regulations” into part 2.

Patient Rights

The Department is finalizing its proposal, with further modification, to require that a part 2 program include in

²¹⁷ See “Individuals' Right under HIPAA to Access their Health Information 45 CFR 164.524,” *supra* note 159.

the Patient Notice statements of patients' rights with respect to part 2 records. The structure mirrors the statements of rights required in the HIPAA NPP for covered entities and PHI but, be based on amended 42 U.S.C. 290dd-2, and patient rights under the final rule. The patient rights listed include, for example, the rights to:

- Request restrictions of disclosures made with prior consent for purposes of TPO, as provided in 42 U.S.C. 290dd-2(b)(1)(C).

- Request and obtain restrictions of disclosures of part 2 records to the patient's health plan for those services for which the patient has paid in full, in the same manner as 45 CFR 164.522 applies to restrictions of disclosures of PHI.

- Obtain an electronic or non-electronic copy of the notice from the part 2 program upon request.

- Discuss the notice with a designated contact person identified by the part 2 program pursuant to paragraph 45 CFR 164.520(b)(1)(vii).

- A list of disclosures by an intermediary for the past 3 years as provided in 42 CFR 2.24.

- Elect not to receive any fundraising communications.

Part 2 Program's Duties

The Department is finalizing its proposal, without modification, to incorporate into the Patient Notice statements describing the duties of part 2 programs with respect to part 2 records that parallel the statements of duties of covered entities required in the HIPAA NPP with respect to PHI.

Although this change is not required by 42 U.S.C. 290dd-2, the statement of duties would put patients on notice of the obligations of part 2 programs to maintain the privacy and security of part 2 records, abide by the terms of the Patient Notice, and inform patients that it may change the terms of a Patient Notice. The Patient Notice also would include a statement of the new duty under 42 U.S.C. 290dd-2(j) to notify affected patients following a breach of part 2 records.

Complaints

The Department is finalizing its proposal, without modification, to require that a part 2 program inform patients, in the Patient Notice, that the patients may complain to the part 2 program and Secretary when they believe their privacy rights have been violated, as well as a brief description of how the patient may file the complaint and a statement that the patient will not be retaliated against for filing a complaint. We are finalizing the

new provision that patients may complain to the Secretary as well as the part 2 program. These changes support the implementation of the CARES Act enforcement provisions, which apply the civil enforcement provisions of section 1176 of the Social Security Act to violations of 42 U.S.C. 290dd-2.

Contact and Effective Date

The Department is finalizing its proposal, without modification, to require that the Patient Notice provide the name or title, telephone number, and email address of a person or office a patient may contact for further information about the part 2 Notice, and information about the date the Patient Notice takes effect. We intend to align compliance dates for any required changes to the HIPAA NPP and part 2 Patient Notice to enable covered entities to make such changes at the same time.

Optional Elements

The Department is finalizing its proposal, without modification, to incorporate into the Patient Notice the optional elements of a HIPAA NPP, which a part 2 program could include in its Patient Notice. This provision permits a program that elects to place more limits on its uses or disclosures than required by part 2 to describe its more limited uses or disclosures in its notice, provided that the program may not include in its notice a limitation affecting its ability to make a use or disclosure that is required by law or permitted to be made for emergency treatment.

Revisions to the Patient Notice

The Department is finalizing the proposal, without modification, to require that a part 2 program must promptly revise and distribute its Patient Notice when there has been a material change and provide that, except when required by law, such material change may not be implemented prior to the effective date of the Patient Notice.

Implementation Specifications

The Department is finalizing its proposal, without modification, to require that a part 2 program provide the § 2.22 notice to anyone who requests it and provide it to a patient not later than the date of the first service delivery, including where first service is delivered electronically, after the compliance date for the Patient Notice. This provision also would require that the notice be provided as soon as reasonably practicable after emergency treatment. If the part 2 program has a physical delivery site, the notice would

have to be posted in a clear and prominent location at the delivery site where a patient would be able to read the notice in a manner that does not identify the patient as receiving SUD treatment, and the Patient Notice would need to be included on a program's website, where available. These provisions would parallel the current requirements for provision of the HIPAA NPP by HIPAA-covered health care providers.

45 CFR 164.520 HIPAA Notice of Privacy Practices

In the NPRM, we proposed to update the HIPAA NPP requirements consistent with requirements in the CARES Act using plain language that is easily understandable. We also proposed additional updates consistent with changes to the HIPAA NPP we proposed in January 2021 (Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement).²¹⁸ This part 2 final rule adopts changes to the part 2 Patient Notice only; it does not include finalized changes to the HIPAA NPP in 45 CFR 164.520. The Department intends to publish modifications to 45 CFR 164.520 as part of a future HIPAA rulemaking. Comments received regarding changes to the HIPAA NPP proposed in the 2022 NPRM will be addressed when those changes are published as part of a HIPAA final rule. As we consider public comments received related to the HIPAA NPP, we intend to carefully consider the progress made by affected entities working to implement changes to the Patient Notice.

Section 2.23—Patient Access and Restrictions on Use and Disclosure

Proposed Rule

In addition to the paragraph (b) changes discussed above in the "use" or "disclosure" section, the Department proposed wording changes to paragraph (b) to improve readability and to replace the phrase "this information" with "records," which more accurately describes the scope of the information to which the regulation applies. The comments and the Department's responses regarding § 2.23 are set forth below.

Comment

While not proposed in the NPRM, a few commenters suggested adding a patient right to direct copies of PHI to a third party, as follows: (1) to define a right to direct copies to prevent

²¹⁸ See 86 FR 6446.

unintended parties from receiving records; (2) to allow covered entities to restrict or refuse requests from any entity that are not the individual or an entity authorized by the individual; and (3) to create a patient right to direct a copy of records to third parties without a consent form to align with HIPAA.

Response

We appreciate the suggestion to create a patient right to direct copies of PHI to a third party; however, that suggestion is outside the scope of the current rulemaking.

Comment

While not proposed in the NPRM, a few commenters also suggested creating a right of access for part 2 records to afford part 2 patients the same rights as individuals under the HIPAA Privacy Rule.

Response

We appreciate the suggestion to create a right of access for part 2 records and the intent to provide equity for those being treated for SUD with respect to their patient rights compared to the rights for patients with other health conditions under HIPAA. This proposal falls outside the scope of the part 2 rulemaking and we did not propose this change or request comment on this topic in the NPRM; therefore, there is not an adequate foundation for adopting a right of access in the final rule.

The HIPAA Privacy Rule established for an individual the right of access to their PHI in a designated record set. The HIPAA right of access applies to records created by a part 2 program that is also a covered entity as well as part 2 records received by a covered entity.²¹⁹ For part 2 programs that are not covered entities, § 2.23 does not prohibit a part 2 program from giving a patient access to their own records, including the opportunity to inspect and copy any records that the part 2 program maintains about the patient.

Comment

One commenter recommended that the Department not adopt the changes proposed to the right of access in its 2021 HIPAA NPRM on coordination of care²²⁰ because the proposed changes “would create new pathways for third parties to easily access patient health information through personal health apps with little to no requirements for patient education and consent, thus eroding longstanding privacy

protections and increasing burden on providers.”

Response

We appreciate the comment; however, the topic is outside the scope of the current rulemaking.

Comment

One commenter appreciated knowing that once they receive SUD records, the records become PHI and are subject to the access requirements in the HIPAA Privacy Rule.

Response

We appreciate the comment. We clarify that when part 2 records are received by or for a covered entity and are part of a designated record set they become PHI and are subject to the HIPAA Privacy Rule access requirements. Generally, the HIPAA Privacy Rule gives individuals the right to access all of their PHI in a designated record set.²²¹ A “designated record set” is a group of records maintained by or for a covered entity that are a provider’s medical and billing records, a health plan’s enrollment, payment, claims adjudication, and case or medical management record systems, and any other records used, in whole or in part, by or for the covered entity to make decisions about individuals.²²² A covered entity’s part 2 records usually fall into one of these categories and thus are part of the designated record set. This is true when a part 2 program is a covered entity, as well as when a covered entity receives part 2 records but is not a part 2 program. As such, the records held by a covered entity are subject to the HIPAA Privacy Rule’s right of access requirements.

Comment

One commenter expressed concerns about any access or disclosures that could subject part 2 patients to criminal charges.

Response

We appreciate this comment. The revisions to § 2.23 clarify the existing prohibition on use and disclosure of information obtained by patient access to their record for purposes of a criminal charge or criminal investigation of the patient.

Comment

One commenter believed that the Department was proposing to remove the written consent requirement for patient access to their own records.

Response

Section 2.23 does not require a part 2 program to obtain a patient’s written consent or other authorization to provide access by the patient to their own records, and the final rule is not changing this. Thus, the ability of a patient to obtain access to their record without written consent will be maintained.

Final Rule

The final rule adopts all proposed modifications to § 2.23(b), without further modification.

Section 2.24—Requirements for Intermediaries

Proposed Rule

The Department proposed to address the role of intermediaries by: (a) creating a regulatory definition of the term in § 2.11; (b) reorganizing the existing requirements for intermediaries and redesignating that provision as § 2.24; and (c) clarifying in § 2.31(a)(4)(ii)(B) how a general designation in a consent for use and disclosure of records to an intermediary would operate. The definition as proposed would read as follows: *Intermediary* means a person who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient. The current part 2 consent requirements in § 2.31 contain special instructions when making a disclosure to entities that fall within the proposed definition of intermediary: the consent must include the name of the intermediary and one of the following: (A) the name(s) of member participant(s) of the intermediary; or (B) a general designation of a participant(s) or class of participants, which must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. The NPRM proposed to replace “entities that facilitate the exchange of health information and research institutions” with “intermediaries” and add “used and” before “disclosed” in § 2.31.

Comment

We received comments both supporting and opposing the Department’s proposal to define “intermediary” and retain consent requirements for disclosures to intermediaries. Most HIEs/HINs and health IT vendors that commented on this set of proposals, expressed concern about our changes. Opposing commenters stated their views that the special provisions for intermediaries

²¹⁹ See “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524,” *supra* note 159.

²²⁰ 86 FR 6446.

²²¹ See 45 CFR 164.524.

²²² See 45 CFR 164.501 (definition of “Designated record set”).

were a holdover from before the CARES Act and were inconsistent with its alignment of part 2 and HIPAA, especially with regard to the new provision to allow a single consent for all future TPO. Some commenters suggested that the CARES Act may require the Department to remove the intermediary provisions. Other commenters believed that these provisions did not support care coordination or were inconsistent with allowing a single consent for TPO.

Commenters asked that we revise the HIPAA definition of “covered entity” to include examples of the intermediaries and remove the part 2 definition of “intermediary”; exclude business associates, health IT vendors, or health plans from the part 2 definition of intermediary; expressly allow intermediaries to disclose for TPO; expressly allow HIEs and HIE participants to be listed in a general designation in the consent for disclosures for TPO; and clarify what types of HIEs or health IT vendors are included in the definition (because some HIE technology or EHR software does not maintain data or have access to it when exchanging data between systems).

One commenter asserted that the CARES Act does not define nor use the term “intermediary” and the Department should instead rely upon established terms of “covered entity,” “business associate,” and part 2 “programs.” Another commenter believed the NPRM created a “two-tiered” system that perpetuates discrimination because patients with SUD cannot reap the benefits of integrated care that is facilitated by shared electronic records. A health plan said that there would not be sufficient oversight of intermediaries under the proposed definition because they include entities that are not subject to HIPAA.

One commenter, a health plan association, asserted that business associates should be carved out from the definition of “intermediary” as most already defined as covered entities or business associates under HIPAA. Others agreed that the role of intermediaries such as HIEs/HINs or ACOs should be carved out from this definition. A few HIE commenters viewed requirements for intermediaries as based on 2017 rule changes, in which the Department attempted to limit those instances when a general designation consent could be used without specifically naming the persons entitled to receive the part 2 record. Additionally, the 2017 rule changes layered on additional accounting and

consent requirements that—together with the operational challenge of determining when and whether a downstream entity has a “treating provider relationship” with the patient—resulted in low adoption due to the technical and administrative challenges in implementing these requirements and limitations. A county department argued that there is no analog to intermediary within HIPAA, thus these changes are inconsistent with the CARES Act effort to foster closer alignment between HIPAA and part 2.

Response

We appreciate input from commenters and have made changes in response to their expressed concerns. Our final definition of “intermediary” in § 2.11 includes “a person, other than a program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient.” We also are finalizing provisions that an intermediary must provide to patients who have consented to the disclosure of their records using a general designation, pursuant to § 2.31(a)(4)(ii)(B), a list of persons to whom their records have been disclosed pursuant to the general designation. These changes will implement the CARES Act consent provisions by permitting HIEs that are business associates to receive part 2 records under a broad TPO consent and redisclose them consistent with the HIPAA regulations. These changes also will encourage HIEs to accept part 2 records and include part 2 programs as participants, facilitate integration of behavioral health information with other medical records, and reduce burdens on business associates that serve as HIEs. Our final rule also is consistent with previous SAMHSA guidance to ensure part 2 data exchanged by HIEs remains subject to protection under this final rule.²²³

Comment

According to one commenter, if a patient signed a consent form designating “my health plan” as the recipient, the part 2 program would be permitted to disclose such information directly to the health plan but would be prohibited from disclosing that information to the very same health plan if the disclosure was made via an

intermediary without specifically naming the intermediary and the health plan. This approach could thus impede operations of HIEs/HINs.

Response

We agree with the commenter’s concerns that the proposed consent requirements for intermediaries may impede HIEs/HINs. The finalized definition of intermediary in § 2.11 excludes part 2 programs, covered entities, and business associates. This approach should help remove barriers to HIEs’/HINs’ inclusion of part 2 records from part 2 programs that are also covered entities. As noted, we believe excluding business associates, in particular, will encourage HIEs to accept part 2 records and include part 2 programs as participants and reduce burdens on business associates that serve as HIEs.

Comment

One HIE commenter said that the NRPM provides an example of an intermediary being an electronic health vendor that enables entities at two different health systems to share records and would be bound by the requirements proposed under § 2.24. However, that same vendor would not be an intermediary when used by employees in different departments of a hospital to access the same patient’s records. The commenter finds this confusing and seeks clarification on the definition of intermediary and their associated requirements. Another commenter, a health IT vendor, also questioned our example in the NPRM claiming that the developer of the product used in an exchange of information is no more an intermediary to the exchange than the manufacturer of a fax machine is an intermediary to information faxed from one place to another. The EHR vendor described in the NPRM should only be considered an intermediary when it controls the exchange of health records between systems using its software or when it serves as the recipient of records.

Response

We acknowledge that some commenters may have found this NPRM example confusing. We believe our revised definition and changes to § 2.24 help clarify the role of intermediaries. We have in the NPRM and other past rules and guidance cited HIEs/health information networks or “HINs,” ACOs, coordinated care organizations, care management organizations, and research institutions as examples of

²²³ See U.S. Dep’t of Health and Human Servs., “Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?” <https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf>.

intermediaries but this may be a fact-specific inquiry.²²⁴

Comment

Other comments on the proposal addressed the role of community-based organizations (CBOs), such as those providing services to people experiencing homelessness. A few commenters requested that such CBOs be considered as intermediaries, and one pointed out that the limitation on sharing part 2 records through an intermediary would likely result in limiting the sharing of records with CBOs via an HIE because CBOs are not treating providers. A county HIE said that it fosters data sharing across dozens of health care providers, managed care, and CBOs to enable better care coordination and to address social determinants of health. The county asserted that allowing part 2 records to be shared based on a single consent for TPO would be “deeply enhanced by pairing it with the technology of an HIE.”

Response

We have noted the definition of “intermediary” and examples above. An intermediary may be named in a general designation in § 2.31(a)(4) though special instructions apply to such use. Under the final rule, we have excluded business associates, part 2 programs, and covered entities from the definition of “intermediary” in § 2.11. Thus, HIEs that meet the definition of “business associates” are not intermediaries.

Part 2 programs, covered entities, and business associates (notably HIEs) are permitted to disclose records for TPO under the new TPO consent requirements and redisclose records as permitted by the HIPAA Privacy Rule once a consent for all future uses and disclosures for TPO is obtained. Accordingly, when a part 2 program that is covered entity discloses records through an HIE, the intermediary consent requirements under § 2.31(a)(4) do not apply because the HIE would be serving as a business associate of the part 2 program/covered entity, and as a business associate the HIE would be excluded from the definition of “intermediary.” We believe that part 2 programs that rely on HIEs are those most likely to be covered entities and to benefit from the narrowed definition of intermediary in the final rule.

Comment

A commenter said that definition of “intermediary” is broad enough that a

primary care provider connecting a patient (and a patient’s part 2 records) from one program to another could be seen as an intermediary. This commenter seeks guidance on the relationship between part 2 programs and intermediaries, and what unintended consequences the Department is seeking to avoid. The commenter suggests collaboration with ONC to leverage TEFCA, as there seems to be overlap between what constitutes an intermediary and how ONC defines a Qualified Health Information Network under TEFCA.

An insurance association referenced TEFCA and said that it is expected to be operating this year, creating a national network for health care information exchange among both HIPAA covered and non-HIPAA covered entities. The part 2 rule, the association said, should be structured to ensure data can be seamlessly shared among covered entities for TPO and other purposes designated in an individual’s consent. However, the commenter believed that robust privacy protections for part 2 records remain critical for all entities involved in health data exchanges. The TEFCA processes are building in governance and operating requirements parallel to the HIPAA privacy and security requirements for all participants in the system even if they are not covered entities under the law to ensure robust protections no matter what role the entity plays. The commenter was concerned that a single weak link in the chain could compromise the entire system.

The commenter also stated that activities by HIEs that go beyond the role of a “basic conduit” should come with commensurate responsibilities for data protections. Therefore, the commenter questioned the definition of “intermediary” as proposed, asserting that it would minimize the accountability of these entities.

Response

We appreciate input from commenters on the role of HIEs and TEFCA. ONC, OCR, SAMHSA and others are collaborating to support participation in TEFCA and implementation of health IT and EHRs within the behavioral health sector.²²⁵ When an HIE is acting as a business associate to a part 2 program that is also a covered entity, it would not be considered an “intermediary” as defined in this final rule because we have excluded business associates (along with programs and covered entities) from the definition. An HIE that is a “business associate” is subject

to certain HIPAA requirements, including safeguards under the HIPAA Security Rule.²²⁶

For clarity, we also explain here that the exclusion of business associates from the “intermediary” definition in § 2.11 results in far fewer entities being subject to intermediary consent requirements under § 2.31(a)(4) and the list of disclosures obligations under § 2.24 because most HIEs—which were the most typical example of an intermediary—are business associates. A QSO—which is analogous to a business associate for a part 2 program—is only considered an intermediary when it is providing services to a program that is not a covered entity. We believe that part 2 programs that are covered entities are those most likely to make use of HIE services and that the burden reduction on HIE business associates in this final rule may incentivize them to accept part 2 records into their systems more frequently than under the existing part 2 regulation.

Comment

SUD recovery organizations recommended modifying the proposed definition of “intermediary” to also include “a member of the intermediary named in the consent,” rather than limiting it to members of the intermediary that have a treating provider relationship with the patient. A state data agency urged us to add intermediaries and other lawful holders to the language of § 2.12(d)(2)(ii), which permitted a non-part 2 treatment provider who receives part 2 information to record it without it becoming a part 2 record, so long as any part 2 records they receive are segregated from other health information.

Response

Section 2.12(d)(2)(ii) applies to persons who receive records directly from a part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on redisclosure in accordance with § 2.32. We are finalizing a modification to this provision to expressly state that: “[a] program, covered entity, or business associate that receives records based on a single consent for all treatment, payment, and health care operations is not required to segregate or segment such records.” Thus, an HIE that is a business associate of a covered entity

²²⁴ *Id.* See also, 87 FR 74216, 74224; 82 FR 6052, 6055.

²²⁵ See “Behavioral Health,” *supra* note 133.

²²⁶ See U.S. Dep’t of Health and Human Servs., “Business Associates” (May 24, 2019), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html>.

that operates a part 2 program cannot, by definition, be an intermediary, and thus would not be required to segregate the part 2 records they receive. However, the records would still be considered part 2 records (as well as PHI) and there is a continuing obligation to protect the records from use or disclosure in proceedings against the patient.

Because the concept of intermediary by its nature is limited to organizations that mediate the interactions between a program and an intended recipient of records, it would not be practical to include in the definition of “intermediary” language concerning “a member of the intermediary named in the consent.”

Comment

Several commenters requested clarification of certain aspects of the proposal, such as: whether entities already subject to HIPAA are included as intermediaries; whether QSOs can serve as intermediaries and how the QSO role would fit into the requirements; whether the intermediary definition is limited to facilitating access for treatment purposes or whether the definition contemplates facilitating access for other purposes (e.g., for payment purposes, patient access, etc.); and which entities have the responsibility for the required list of disclosures and exactly which responsibilities related to that requirement. One commenter requested that the Department expressly clarify that QSOs are not intermediaries since QSOs do not receive records under a general designation in a written patient consent, but rather they receive records through a QSOA.

Response

We discuss our changes to the definition of “intermediary” here and in § 2.11. As noted, in response to public comments we are excluding covered entities, business associates, and part 2 programs from the definition of “intermediary.” Further, the “intermediary” definition is not, in and of itself, expressly limited to facilitating access for treatment purposes; however, by the operation of the consent requirement in § 2.31, the use of intermediaries is generally limited to facilitating the exchange of records among treating providers. The final rule definition of “qualified service organization” includes a person who meets the definition of “business associate” in 45 CFR 160.103, for a part 2 program that is a covered entity, with respect to the use and disclosure of PHI that also constitutes a part 2 record.

Expressly including business associates as QSOs, where both definitions are met, responds to comments received on the NPRM noting that the role of QSOs is analogous to business associates, such that aligning terminology makes sense given the purpose of section 3221 of the CARES Act to enhance harmonization of HIPAA and part 2. Additionally, as commenters requested, we have carved out business associates from the definition of “intermediary.” Thus, while a QSO may be a business associate, it cannot at the same time also be considered an intermediary. As a result, an HIE/HIN that is a QSO and business associate for a part 2 program that is also a covered entity would not be subject to the intermediary requirements (e.g., a general designation in a consent and the list of disclosures).

Comment

About half of the commenters on intermediaries opposed the requirement that intermediaries provide a list of disclosures for the 3 years preceding the request. Many commenters expressed concern that the TPO consent provisions in §§ 2.31 and 2.33 would result in an increase in requests for a list of disclosures made via an intermediary and that HIEs were not equipped to respond in volume. One commenter opined that millions of transactions will be facilitated by the intermediary daily and, as a result, it would be difficult for both the part 2 program and the intermediary to provide a full accounting of disclosure that would feasibly be usable and helpful to the patient. Others suggested the part 2 program directly assume this obligation.

While supporting the proposed changes, a few commenters raised substantial concerns about the existing requirements, stating that it would be difficult for an intermediary to log individual accesses and reasons why data was accessed over a multi-year period. While patients should understand where and how their data is being transferred, it must be done while maintaining the interoperability pathway outlined by other HHS programs and with the full understanding of burden represented. A few commenters specifically supported the proposed extension for the list of disclosures from 2 to 3 years. A local government and a health system appreciated that the obligation for producing the list of disclosures remains with the intermediary and not the part 2 program. A few commenters asserted that the proposed changes would help address technological issues with HIEs that are compliant with part 2. Others suggested this process would

be burdensome for HIEs and part 2 programs.

Response

We acknowledge these comments. The final rule in § 2.24 extends the “look back” period for the required list of disclosures by an intermediary from 2 years to 3 years as proposed. We made this change to align with the new right to an accounting of disclosures in § 2.25 for disclosures made with consent, that contains a 3-year look back period. As we have stated prior to this final rule, the intermediary, not the part 2 program itself, is responsible for compliance with the required list of disclosures under § 2.24.²²⁷ We discuss costs and benefits associated with this rule below including for §§ 2.24 and 2.25.

Comment

Comments asserted that the accounting requirement for intermediaries was duplicative of the accounting of disclosure for TPO from an EHR requirements under HIPAA (which have not been finalized in regulation) and had created barriers to the use of HIEs to exchange part 2 records. One commenter asserted that they have not allowed part 2 records in their system due to the differing requirements and that the intermediary proposal would perpetuate this outcome. Another commenter explained that a group of organizations that tested part 2 disclosure models did not ultimately adopt them because the part 2 requirements were too problematic. Several commenters requested that the requirement for providing the list of disclosures be tolled until the finalization of the expected HIPAA accounting of disclosures regulation for TPO disclosures through an EHR.

Response

We are not tolling the list of disclosures requirements for intermediaries because these obligations already exist in § 2.13(d) and are simply being continued in a new section § 2.24 with the time period covered being extended from 2 years to 3. Intermediaries are not subject to the HIPAA accounting of disclosures requirements, by definition, because we have excluded covered entities and business associates from the definition of “intermediary” in the final rule. Because the HIPAA accounting of disclosures requirement for TPO disclosures through an EHR has not yet been finalized, we believe this distinct list of disclosures requirement should remain effective.

²²⁷ 82 FR 6052, 6072.

Final Rule

We are finalizing in this section, redesignated as § 2.24, that an intermediary must provide to patients who have consented to the disclosure of their records using a general designation pursuant to § 2.31(a)(4)(ii)(B), a list of persons to whom their records have been disclosed pursuant to the general designation.

Section 2.25—Accounting of Disclosures

Proposed Rule

The Department noted in the NPRM that except for disclosures made by intermediaries, the current part 2 regulation did not have provisions that included a right for patients to obtain an accounting of disclosures of part 2 records.²²⁸ Section 290dd–2(b)(1)(B) of 42 U.S.C., as amended by section 3221(b) of the CARES Act, applies section 13405(c) of the HITECH Act, 42 U.S.C. 17935(c) (Accounting of Certain Protected Health Information Disclosures Required if Covered Entity Uses Electronic Health Record), to part 2 disclosures for TPO with prior written consent. Therefore, the Department proposed to add a new § 2.25 (Accounting of disclosures) to establish the patient's right to receive, upon request, an accounting of disclosures of part 2 records made with written consent for up to three years prior to the date the accounting is requested.

This proposal was intended to apply the individual right to an accounting of disclosures in the HITECH Act to disclosure of part 2 records.²²⁹ The Department proposed at § 2.25(a) that paragraph (a) would generally require an accounting of disclosures made with patient consent for a period of 6 years prior to the request, and paragraph (b) would limit the requirement with respect to disclosures made with TPO consent, which would only be required for disclosures made from an EHR system for a period of 3 years prior to the request. In both instances, the proposed changes would be contingent on the promulgation of HITECH Act modifications to the accounting of

disclosures standard in the HIPAA Privacy Rule at 45 CFR 164.528.²³⁰

The Department stated in the NPRM preamble that this proposed accounting requirement is consistent with section 3221(b) of the CARES Act, 42 U.S.C. 290dd–2(b)(1)(B), as amended. The Department noted that the CARES Act applied the HITECH Act “look back” time period for accounting of disclosures to “all disclosures” of part 2 records with consent and not just those disclosures contained in an EHR. From a policy perspective, the Department therefore proposed to apply the 3-year “look back” to all accountings of disclosures with consent and not just for accountings of disclosures of records contained in an EHR.

Because the Department has not yet finalized the HITECH Act accounting of disclosures modifications within the HIPAA Privacy Rule, the Department did not propose to require compliance with § 2.25 before finalizing the HIPAA Privacy Rule provision in 45 CFR 164.528. The comments and the Department's responses regarding § 2.25 are set forth below.

Accounting of Disclosures for TPO

Comment

A few commenters expressed opposition to the accounting of disclosures for TPO because: (1) the proposal does not align with the HIPAA Privacy Rule, including the exclusion pursuant to an authorization; (2) it would increase administrative burden; and (3) the existing and established technology lacks the capability, including manual collection of data from multiple systems (e.g., EHR and practice management system for payment and health care operations). Other commenters remarked that unless technical capabilities are developed within certified EHR technology to capture why someone has opened a patient record, providing a full accounting would be impossible and requiring providers to mark and

maintain a full accounting would incentivize providers to forego going into a patient's record, even when it may be better for treatment coordination.

Response

We appreciate the comments. However, the proposed change is required by section 290dd–2(b)(1)(B) of 42 U.S.C., as amended by section 3221(b) of the CARES Act, that applies section 13405(c) of the HITECH Act, 42 U.S.C. 17935(c), to part 2 disclosures for TPO with prior written consent. The final rule attempts to balance the potential compliance burden by tolling the effective and compliance dates for the HITECH accounting of disclosures requirement until it is finalized within the HIPAA Privacy Rule.

Comment

A health system and a health IT vendor commented on the timeframes covered in accountings of disclosure and suggested that the period for which accountings can be requested be limited to those after the rule is effective because of different applicable privacy standards prior to rule finalization. For example, if the Department finalizes the accounting of disclosures provision to include data for six years prior to the request date, the first day for which part 2 programs would need to provide accountings would be the effective date of the rule.

Response

We appreciate the comments. We clarify that the period for which an accounting can “look back” is limited to those disclosures occurring after the first day of the compliance date.

Comment

An HIE association requested the Department provide a specific maximum allowable cost to a patient for fulfilling a requested accounting of disclosures for their PHI in the final rule. According to the commenter, the Department provides guidance in other resources on the maximum allowable cost that a patient can incur when requesting an accounting of disclosures but the NPRM did not provide a clear and concise regulatory specification.

Response

We appreciate the comment and decline at this time to state a maximum patient cost; however, we will further consider the comment in drafting the HIPAA accounting of disclosures final rule to implement section 13405(c) of the HITECH Act, 42 U.S.C. 17935(c). We are not aware of resources that discuss

²²⁸ 42 CFR 2.13(d) (specifying List of Disclosures requirement applicable to intermediaries).

²²⁹ OCR published an NPRM to implement this HITECH Act provision in 2011 but did not finalize it because of concerns raised by public comments. See 76 FR 31426 (May 31, 2011). OCR announced its intention to withdraw the 2011 NPRM and requested public input on new questions to help OCR implement the HITECH Act requirement as part of the 2018 HIPAA Rules Request for Information (RFI). See 83 FR 64302, 64307 (Dec. 14, 2018). A final HIPAA regulation on the accounting of disclosures that would apply to TPO disclosures by covered entities has not been issued.

²³⁰ See also sec. 13405(c) of the HITECH Act (codified at 42 U.S.C. 17935(c)). Since the HITECH Act requirement for accounting of disclosures was enacted in 2009, the Department published a RFI at 75 FR 23214 (May 3, 2010) and an NPRM at 76 FR 31426 (May 31, 2011). Based in part on public comment on the RFI, the Department proposed to provide individuals with an “access report” as a means of fulfilling the requirement. Based on feedback on the NPRM in which commenters overwhelmingly opposed the report as “unworkable,” the Department, in a follow up RFI published at 83 FR 64302, explained its intent to withdraw the proposal of the 2011 NPRM. The Department received additional public comment about implementing sec. 13405(c) and will publish in a future Regulatory Unified Agenda notice about any future actions.

the maximum allowable cost that a patient can incur when requesting an accounting of disclosure. However, the Department has provided guidance in other resources on the costs a covered entity may charge individuals to receive a copy of their PHI, which is a different cost from providing individuals an accounting of disclosures. For an accounting of disclosures, the HIPAA Privacy Rule at 45 CFR 164.528(c)(2) requires a covered entity provide the first accounting to an individual in any 12-month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12-month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request.

Comment

Several commenters were supportive of the proposal to add a new accounting of disclosures requirement in part 2 because it would align with an individual's rights under the HIPAA Privacy Rule. One health IT vendor said health IT and other digital technologies should incorporate audit trails to help detect inappropriate access to PHI. An advocacy organization supported the proposed timeframes an accounting of disclosures would cover, while a health system said the three-year timeframe for TPO disclosures should match the six-year timeframe in the HIPAA Privacy Rule.

Response

We appreciate the comments. With respect to the “look back” period for accounting of disclosures in the HIPAA Privacy Rule, an individual has a right to receive an accounting of disclosures of PHI made by a covered entity in the six years prior to the date on which the accounting is requested.²³¹ The HITECH accounting requirement covers disclosures for TPO made via an EHR and a look back period of only three years; however, this has not been finalized in the HIPAA Privacy Rule, so we cannot harmonize the part 2 TPO disclosure timeframe to that of the HIPAA Privacy Rule accounting of disclosure requirement. Additionally, a HIPAA accounting of disclosures rulemaking would implement the HITECH Act modification to 45 CFR 164.528 for disclosures for TPO to three

years prior to the date which the accounting is requested.²³²

Comment

A few trade associations and a health IT vendor requested the Department provide a template for the accounting of disclosures that includes the level of detail necessary to fulfill the requirement.

Response

We appreciate the comments and will consider providing a template when the HITECH accounting of disclosures requirement is finalized within the HIPAA Privacy Rule.

Tolling of Compliance Date

Comment

A few commenters addressed tolling the compliance date for part 2 programs and each of them agreed with tolling the effective and compliance dates of the accounting of disclosures proposal until the effective and compliance dates of the modified HIPAA Privacy Rule accounting provision to provide consistency for part 2 providers, covered entities, and business associates.

Response

We appreciate the comments. We are tolling the effective and compliance dates for part 2 programs until the effective and compliance dates of a final rule on the HIPAA/HITECH accounting of disclosures standard (section 13405(c) of the HITECH Act) to ensure part 2 programs do not incur new compliance obligations before covered entities and business associates under the HIPAA Privacy Rule are obligated to comply. We are also mindful that the alignment of the part 2 and HIPAA compliance dates for the accounting of disclosures is most important for part 2 programs that are also covered entities. We also note the part 2 programs are not required to include the statement of a patient's right to an accounting of disclosures in the Patient Notice under § 2.22 until the future compliance date of the accounting of disclosures.

Other Comments on Requests for Accountings of Disclosures

The Department, in the NPRM, asked for feedback on potential burdens such as staff time and other costs associated with accounting of disclosure requests.²³³ The Department also requested data on the extent to which covered entities receive requests from

patients to restrict disclosures of patient identifying information for TPO purposes, how covered entities document such requests, and the procedures and mechanisms used by covered entities to ensure compliance with patient requests to which they have agreed or that they are otherwise required to comply with by law.

Comment

A few commenters said they rarely receive requests for an accounting of disclosures and a few commenters stated they receive between 1–10 requests annually. Some of these commenters said in their experiences a single request for an accounting of disclosures from a patient may take one staffer with the current functionality within an organization a full 40-hour week to respond.

Response

We appreciate the comments and the information provided on the number and type of requests for an accounting of disclosures of PHI received annually and the staff time involved in responding to an individual's request for an accounting of disclosures of PHI.

Final Rule

The final rule adopts all proposed modifications to § 2.25, with a correction to the timeframe in paragraph (a) to require an accounting of disclosures made with consent in the 3 years prior to the date of the request.

Section 2.26—Right to Request Privacy Protection for Records

Proposed Rule

Prior to the CARES Act amendments, the part 2 statute did not explicitly provide a patient the right to request restrictions on disclosures of part 2 records for TPO, although patients could tailor the scope of their consent, which would govern the disclosure of their part 2 records. Section 3221(b) of the CARES Act amended 42 U.S.C. 290dd–2 such that section 13405(c) of the Health Information Technology and Clinical Health Act (42 U.S.C. 17935(c)) applies to subsection (b)(1). Therefore, the Department proposed to codify in § 2.26 a patient's rights to: (1) request restrictions on disclosures of part 2 records for TPO purposes, and (2) obtain restrictions on disclosures to health plans for services paid in full. The proposed provision would align with the individual right in the HITECH Act, as implemented in the HIPAA Privacy Rule at 45 CFR 164.522.²³⁴ As with the HIPAA Privacy Rule right to request

²³² See sec. 13405(c) of the HITECH Act (codified at 42 U.S.C. 17935(c)).

²³³ 87 FR 74216, 74239, 74249.

²³⁴ See 42 U.S.C. 17935(a).

²³¹ See 45 CFR 164.528(a)(3).

restrictions, a part 2 program that denies a request for restrictions still would be subject to any applicable state or other law that imposes greater restrictions on disclosures than part 2 requires.

In addition to applying the HITECH Act requirements to part 2, the CARES Act emphasized the importance of the right to request restrictions in three provisions, including:

(1) a rule of construction that the CARES Act should not be construed to limit a patient's right under the HIPAA Privacy Rule to request restrictions on the use or disclosure of part 2 records for TPO;²³⁵

(2) a Sense of Congress that patients have the right to request a restriction on the use or disclosure of a part 2 record for TPO;²³⁶ and

(3) a Sense of Congress that encourages covered entities to make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding TPO uses or disclosures of part 2 records.²³⁷

Comment

Commenters provided general support for the proposal to modify part 2 to implement requirements in the CARES Act concerning a patient's right to request restrictions on uses and disclosures of part 2 records. For instance, a medical professionals association supported this proposed change, stating that transparent privacy policies should accommodate patient preference and choice as long as those preferences and choices do not preclude the delivery of clinically appropriate care, public health, or safety. A county health system said the proposed changes will promote patient advocacy, privacy, and transparency. Health system and health plan commenters supported the proposed language allowing patients to request restrictions on the use or disclosure of their PHI if this request aligns with the HIPAA Privacy Rule, which gives covered entities the ability to approve or deny these requests. Others such as state agencies, health care providers, and a health IT vendor also supported provisions to request restrictions on disclosures including for disclosures otherwise permitted for TPO purposes.

Response

We appreciate the comments about the proposed addition of a new patient

right to request restrictions on uses and disclosures of part 2 records for TPO and the alignment of the right with the parallel HIPAA provision.

Comment

A health information association supported a mechanism for patients to request to restrict where and who can access their records in specific situations as this approach builds trust and allows the patient to control use and disclosure of their health record. The commenter further asserted that while data segmentation challenges exist, most providers follow HIPAA and align with state law privacy requirements regarding use and disclosure of part 2 records. However, the association urged that as the Department finalizes these requirements the ability for a patient to request restriction of disclosure should not be mandatory for providers to adhere to when they are otherwise required to provide disclosure. Another provider supported aligning the right to request a restriction with HIPAA language to include specific language which clarifies a covered entity and/or part 2 program is under no obligation to agree to requests for restrictions. Due to EHR functionality limitations, the provider cannot accommodate most requests for restrictions, especially related to treatment.

Response

We appreciate the comments about our proposed change to align part 2 and HIPAA requirements. As stated in § 2.26(a)(5): “[a] restriction agreed to by a part 2 program under paragraph (a) of this section is not effective under this subpart to prevent uses or disclosures required by law or permitted by this regulation for purposes other than treatment, payment, and health care operations, as defined in this part.” Paragraph (a)(6) of § 2.26 also states that “[a] part 2 program must agree to the request of a patient to restrict disclosure of records about the patient to a health plan if . . . [t]he disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law [. . .].” Therefore, a part 2 program that is a covered entity is not required by this section to agree to restrict a disclosure that otherwise is required by law²³⁸ or for a purpose permitted by part 2 other than TPO.²³⁹

²³⁸ For further discussion of “required by law” in the HIPAA context, see 78 FR 5566, 5628.

²³⁹ For further discussion of “required by law” in the HIPAA context, see 78 FR 5566, 5628.

Comment

An individual commenter urged the Department to expand its proposal by using the general regulatory authority given it by the CARES Act to modify 42 CFR part 2 to indicate that a covered entity is required to agree to a patient's requested restriction of uses and disclosures of part 2 information. Thus, the commenter suggested the provisions of 45 CFR 164.522(a)(1)(ii) and (a)(2)(iii) would be eliminated. The commenter asserted that a “rule of construction” in the CARES Act should not be construed to limit a patient's right under the HIPAA Privacy Rule to request restrictions on the use or disclosure of part 2 records for TPO. The commenter stated its interpretation of the Sense of Congress in the CARES Act that patients have the right to request a restriction on the use or disclosure of a part 2 record for TPO and that encourages covered entities to make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding TPO uses or disclosures of part 2 records.

A health system also supported this change stating that this provision aligns with existing standards under the HIPAA Privacy Rule, which allows a patient to request restrictions, while a covered entity is not obligated to agree to that request (except when the service in question has been paid in full). The health system appreciated that HHS proposed to allow the same flexibility and decision-making capacity for part 2 programs. Another commenter proposed that the same standards are applied in part 2 as in HIPAA, which requires covered entities to evaluate requests and take reasonable means. The commenter believed that a covered entity is not mandated to honor a restriction for purposes of operation/treatment but would be for payment in circumstances where the patient pays out of pocket, in full. The commenter suggested applying the same standards to part 2 as applied to covered entities in the HIPAA restriction process. A health system said it supported aligning part 2 and HIPAA, but if there is a part 2 entity that is not already a covered entity under HIPAA, HHS should expand the HIPAA definition of covered entity rather than duplicate HIPAA provisions in this rule.

Response

We acknowledge these comments and emphasize the Sense of Congress expressed in section 3221(k)(3) of the CARES Act that “[c]overed entities should make every reasonable effort to the extent feasible to comply with a

²³⁵ See sec. 3221(j)(1) of the CARES Act. The Department believes the effect of this rule of construction is that 45 CFR 164.522 of the HIPAA Privacy Rule continues to apply without change to covered entities with respect to part 2 records.

²³⁶ See sec. 3221(k)(2) of the CARES Act.

²³⁷ See sec. 3221(k)(3) of the CARES Act.

patient's request for a restriction" regarding such use or disclosure.

Comment

A health system citing to 42 CFR 2.12(c)(3) supported HHS' attempt to better align part 2 with HIPAA as it relates to both uses and disclosures, stated that the introduction of restrictions on uses poses significant challenges for part 2 programs unless additional changes or clarifications to the regulations are made. The commenter urged the Department to clarify in the final rule that permitted uses also include those uses necessary to carry out the payment or health care operations of the part 2 program. Such clarification will ensure part 2 programs may continue to use part 2 records internally for payment and health care operations that may not directly relate to the diagnosis, treatment, or referral for treatment of patients. Without this clarification, if a part 2 program fails to secure consent from a patient, the part 2 program would be prohibited from using part 2 records for essential internal purposes, such as quality improvement, peer review, and other legally required patient safety activities.

Response

Section 2.12(c)(3), which excludes from part 2 restrictions treatment-related internal communications among staff in a program and communications with entities that have direct administrative control of the program, is not inconsistent with the new patient right to request restrictions on disclosures for TPO purposes, and a patient's right to obtain restrictions on disclosures to health plans for services paid in full by the patient. Additional changes desired by the commenter to § 2.12(c)(3) are outside the scope of this rulemaking.

Comment

A medical professionals association asserted that given the sensitivity of SUD data patients may request that their SUD treatment data not be shared with other clinicians nor be accessible via various third-party applications. The commenter believed that physicians, especially those in primary care, generally lack the ability to segment out certain parts of a patient's record while maintaining the ability to meaningfully share the non-SUD treatment data with the patient's care team for the purposes of care coordination and management. The commenter explained its view that this lack of granular data segmentation functionality increases administrative burden and creates challenges for clinicians who are complying with

requests not to disclose SUD treatment data while still complying with HIPAA and information blocking requirements. As a result, clinicians must either place sensitive data in the general medical record and institute policies and procedures outside of the EHR to protect this data or create a new location or shadow chart that houses and protects the data. These workarounds disrupt the flow of comprehensive health data within a patient's care team and increases administrative tasks. The association urges HHS to work with EHR vendors to modernize the functionality of health care data management platforms to ensure part 2 programs can keep patients' data confidential when requested. Another medical association also reflected similar views.

A health IT vendor claimed that several NPRM provisions, including § 2.26, would require it to implement procedural changes. But the vendor stated that these updates are necessary to eliminate barriers to data sharing amongst patients, providers, and health care facilities. The vendor also believed these requirements can be implemented within the proposed 22-month compliance period.

A health IT association supported alignment with a patient's right to request restrictions under the existing HIPAA Privacy Rule. But the commenter believed that it is important not to add a burden on covered entities participating in a shared electronic health information platform or with an HIE or HIN. The commenter urged OCR and SAMHSA to connect to health IT developers, technology companies, HIE, and HINs to ensure that technology exists to feasibly allow for covered entity compliance with interoperability and information blocking requirements.

Response

We acknowledge concerns that data segmentation may be difficult for part 2 programs and covered entities and discuss this further in § 2.12. However, covered entities have had to address individuals' requests for restrictions of TPO uses and disclosures since the HIPAA Privacy Rule was implemented more than two decades ago. The renewed emphasis on the right to request restrictions on uses and disclosures of records for TPO is closely linked to the new permission to use and disclose records based on a single consent for all future TPO. We have stated in the discussion of the new consent permission that programs and covered entities that want to utilize the TPO consent mechanism should be prepared from a technical perspective to

also afford patients their requested restrictions when it is otherwise reasonable to do so. Entities that are planning to benefit from streamlined transmission and integration of part 2 records by using the single consent for all TPO should be prepared to ensure that patients' privacy also benefits from the use of health IT.

EHR systems' technical capabilities are outside the scope of this rulemaking, but we are cognizant of and refer throughout this rule to the existing health IT capabilities supported by data standards adopted by ONC on behalf of HHS in 45 CFR part 170, subpart B, and referenced in the ONC Health IT Certification Program certification criteria for security labels and segmentation of sensitive health data. ONC, SAMHSA, OCR, and others collaborate to support EHRs and health IT in behavioral health and integrated care settings.²⁴⁰

Comment

A provider association opined that the NPRM overemphasizes the social harms that disclosing SUD clinical information creates, at the risk of medical harms and overdose deaths that are a consequence of poor care coordination. The commenter urged the Department to provide guidance on precisely what is expected of providers as they incorporate processes to respect these patient rights if the provisions are finalized as proposed.

Response

We appreciate this comment and the concern for patient safety. As noted above, providers are not required to agree to all patient requests for restrictions on uses and disclosures for TPO, but are encouraged to make reasonable efforts to do so. Providers retain the responsibility for patient care and determining what is reasonable under the circumstances. The final rule is emphasizing, however, that programs and covered entities are expected to do more than merely establish policies and procedures on the right to request restrictions—they need to make a concerted effort to evaluate how they can reasonably accommodate patients' requests.

Comment

An academic health center stated its general support for patients' rights to limit access to their medical records but wanted to avoid creating further administrative and operational burdens on staff and avoid managing patient data retroactively.

²⁴⁰ See "Behavioral Health," *supra* note 133.

Response

We acknowledge this comment and concerns about burdens that could result from § 2.26 implementation. However, part 2 programs that are covered entities are already subject to the HIPAA provisions on the right to request restrictions in 45 CFR 164.522. As finalized, we believe this section is consistent with HIPAA as well as CARES Act requirements.

Comment

A medical professionals association asserted that the NPRM does not account for patient protections in plans self-funded through an employer. The association requested clarity on how TPO information will be kept protected from the employer and how patients will be protected against discriminatory practices, arguing that without further clarification, employees will be hesitant to seek treatment if there is an assumption that an employer will have knowledge of his or her SUD.

In contrast, a national employee benefits association for large employers urged the Department to allow health plan sponsors (*i.e.*, employers) to access part 2 records containing de-identified claims data that are held by third-party vendors that manage SUD programs. From the employer/health plan sponsors' perspective, these records are needed to evaluate and improve health benefits.

Response

Self-funded group health plans are not permitted to retaliate against SUD or other patients/employees for seeking care. HHS has explained in guidance application of HIPAA to self-funded employer group health plans that: "the [HIPAA] Privacy Rule does not directly regulate employers or other plan sponsors that are not HIPAA covered entities. However, the [HIPAA] Privacy Rule, in 45 CFR 164.504(f) does control the conditions under which the group health plan can share protected health information with the employer or plan sponsor when the information is necessary for the plan sponsor to perform certain administrative functions on behalf of the group health plan [. . .] The covered group health plan must comply with [HIPAA] Privacy Rule requirements, though these requirements will be limited when the group health plan is fully insured."²⁴¹

²⁴¹ U.S. Dep't of Health and Human Servs., "As an employer, I sponsor a group health plan for my employees. Am I a covered entity under HIPAA?" (Apr. 6, 2004), <https://www.hhs.gov/hipaa/for-professionals/faq/499/am-i-a-covered-entity-under-hipaa/index.html>.

In discussing 45 CFR 164.530, HHS has further stated in guidance that "group health plans are exempt from most of the administrative responsibilities under the [HIPAA] Privacy Rule. These health plans are still required, however, to refrain from intimidating or retaliatory acts, and from requiring an individual to waive their privacy rights."²⁴²

As well, self-funded group health plans are subject to the Mental Health Parity and Addiction Equity Act (MHPAEA) which requires that most health plans providing mental health and SUD benefits must provide services comparable to those for medical/surgical conditions.²⁴³ While previously able to opt-out of these requirements, recent changes made by the Consolidated Appropriations Act of 2023 state that "self-funded, non-Federal governmental group health plans that opt out of compliance with MHPAEA are required to come into compliance with these requirements."²⁴⁴ This change too should mitigate the potential of employees to be subject to stigma and discrimination within self-funded group health plans because they have or are in recovery from an SUD.

With respect to employer/health plan sponsor access to de-identified part 2 records, the Department did not propose to create new use and disclosure permissions specific to employers/health plan sponsors and does not adopt such changes in this final rule. However, under this final rule, a covered entity or business associate that receives records under a TPO consent may redisclose them in accordance with the HIPAA Privacy Rule, which does not place limitations on the use or disclosure of de-identified information.

²⁴² See U.S. Dep't of Health and Human Servs., "I'm an employer that offers a fully insured group health plan for my employees. Is the fully insured group health plan subject to all of the Privacy Rule provisions?" (Apr. 6, 2004), <https://www.hhs.gov/hipaa/for-professionals/faq/496/is-the-fully-insured-group-health-plan-subject-to-all-privacy-rule-provisions/index.html>.

²⁴³ See Ctrs. for Medicare & Medicaid Servs., "The Mental Health Parity and Addiction Equity Act (MHPAEA)," https://www.cms.gov/ccio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet; Ctrs. for Medicare & Medicaid Servs., "Sunset of MHPAEA opt-out provision for self-funded, non-Federal governmental group health plans" (June 7, 2023), <https://www.cms.gov/files/document/hipaa-opt-out-bulletin.pdf>.

²⁴⁴ Ctrs. for Medicare & Medicaid Servs., "Sunset of MHPAEA opt-out provision for self-funded, non-Federal governmental group health plans," at 1 (June 7, 2023), <https://www.cms.gov/files/document/hipaa-opt-out-bulletin.pdf>. See also, 42 U.S.C. 300gg-26, Parity in mental health and substance use disorder benefits.

Comment

A health plan asserted that, as written, the rule might be interpreted to prevent plans with part 2 data from redisclosing it without consent. Additional restrictions around TPO may negatively impact plans' business operations since plans would need to separate part 2 records from other records. This restriction would be burdensome and more operationally challenging even for the most sophisticated stakeholders, according to the commenter, who also asserted that patients may be more likely to receive unnecessary information in these broad disclosures. The commenter believed that the proposed expanded TPO restriction would overwhelm both patients and plans, ultimately hindering efforts toward more efficient care coordination for patients with SUD.

Response

This section as finalized is consistent with the Sense of Congress as articulated in the CARES Act, which provides that patients have the right to request a restriction on the use or disclosure of a part 2 record for TPO. The CARES Act similarly encourages covered entities to make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding TPO uses or disclosures of part 2 record.

A patient's right to request restrictions does not prevent health plans with part 2 records from redisclosing such records without patient consent as permitted under this rule, except in those situations where the plan has agreed to a requested restriction.

Comment

A few commenters, including an advocacy organization, professional associations, and a recovery organization asserted that the proposed right is profoundly inequitable because it is only available to patients with the means to pay privately for SUD treatment. Pointing to what it views as disparities and the cost of SUD treatment, one commenter asserted that underserved communities and persons affected by poverty and inequality thus will be less able to exercise this right to restrict uses and disclosures of their SUD records. Other commenters expressed concern that some patients can afford to self-pay and may not wish to face the risks of restrictive health plan coverage policies, employers, and others finding out they are being treated for an SUD, but this right is not extended to those who cannot self-pay. These commenters believed that the rule

should not subject most Americans to these very real risks while acknowledging that persons of means can avoid them.

The commenter recommended that HHS strengthen this provision so that providers comply with all patients' requests to restrict disclosures of this sensitive health information—not just those patients who are wealthy enough to pay in full and out-of-pocket. The commenter argued that strengthening the provision is also consistent with the CARES Act's "Sense of Congress" in section 3221(k)(3): "covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure." The commenter asserted that when patients request a restriction on disclosure of their part 2 records, the default answer should be "yes," subject to narrow exceptions such as disclosures to treat a medical emergency. In practice, however, providers' default answer is almost always "no," which is why HHS should provide a more enforceable right here.

Response

We acknowledge that, as structured, some elements of the right to request restrictions may benefit patients who can self-pay rather than those who are unable to do so. However, the provision requiring covered entities to agree to certain requests is statutory. For this reason and to align with HIPAA requirements pertaining to requests for restrictions by self-pay patients.²⁴⁵ The Department also acknowledges and is working to address disparities in access to SUD treatment.²⁴⁶

Comment

One county government stated that in its experience there are very few requests for restriction received each year and virtually none are agreed to because of the related operational challenges. An academic health center said that in its experience of patients who request restrictions annually, only

a relatively small number of restrictions are made in the context of self-pay for services. The center urged HHS to align the request for restriction process for part 2 records with what it views as the already established and operationally familiar process under HIPAA, explaining that from a technological perspective restricting patient information within the organization for TPO is burdensome, and highly error-prone. Restrictions for treatment purposes can endanger patients, as members of the treatment team need information to safely provide care, according to this commenter.

Response

We appreciate this information in response to our request for input in the NPRM. Given that the number of requests for restrictions is small, the overall organizational burden for fulfilling such requests should not be overwhelming. When a regulated entity agrees to a requested restriction, we encourage it to explain to the patient any limits on its ability to ensure that the request is implemented fully.

Comment

A commenter requested that notice of the right to request limitations of disclosures of health records, and the process for doing so comply with Federal guidance and best practices for individuals with limited English proficiency and individuals with limited literacy or health literacy skills.

Response

We discuss notice requirements in § 2.22 above. We have in the past stated that materials should take into consideration the cultural and linguistic needs of a provider's patients and be written to be clear and understandable.²⁴⁷

Comment

A privacy foundation cited one of its resources concerning HIPAA and why the right to request restrictions is in its view almost meaningless. The commenter suggested that the rule does not require a covered entity to agree to a restriction requested by a patient. More importantly, the covered entity does not have to agree even if the patient's request is reasonable. If HHS does not require a covered entity to respond to a patient's request for restriction, even to state whether the request is granted or declined, the right to request restrictions is meaningfully diminished, according to the commenter, which, added that in some

cases, the right to request restrictions will be—for all intents and purposes—abrogated in cases where the request is never given any response.

Response

As finalized, we believe this section is consistent with HIPAA as well as CARES Act requirements. We have provided guidance within HIPAA about requests for restrictions on disclosures of PHI in HIPAA under 45 CFR 164.522.²⁴⁸ The right to request restrictions must be balanced with other regulatory requirements and patient needs, such as for emergency treatment even when use of records has been restricted. We also note that as required by § 2.26(a)(6)(ii), a part 2 program must implement restrictions on disclosure when requested by a patient if a record pertains solely to a health care item or service for which the patient, or person other than the health plan on behalf of the patient, has paid the part 2 program in full.

Comment

An SUD provider recommended eliminating the ability for tailored restrictions by patients. Additionally, should the Department implement this requirement, the provider requests requested that the regulations clarify whether a part 2 program is responsible for notifying other recipients of part 2 information if a patient decides to restrict future disclosures.

Response

As explained, we are finalizing the proposed requirements. Redisclosure provisions are discussed in this rule in §§ 2.12(d) and 2.33. As we note, consistent with the Sense of Congress in the CARES Act, section 3221(k)(3), covered entities, including those covered entities that also are part 2 programs, should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding a particular use or disclosure. This would apply should a patient subsequently modify a request under this section.

Comment

An advocacy group supported the proposed right of patients to request privacy protections as a means of

²⁴⁵ U.S. Dep't of Health and Human Servs., "Under HIPAA, may an individual request that a covered entity restrict how it uses or discloses that individual's protected health information (PHI)?" (Dec. 28, 2022), <https://www.hhs.gov/hipaa/for-professionals/faq/3026/under-hipaa-may-an-individual-request-that-a-covered-entity-restrict-how-it-uses-or-discloses-that-individuals-protect-health-information/index.html>.

²⁴⁶ See, e.g., Substance Abuse and Mental Health Servs. Admin., "Behavioral Health Equity," <https://www.samhsa.gov/behavioral-health-equity>; Off. of the Assistant Secretary for Planning and Evaluation, "Meeting Substance Use and Social Service Needs in Communities of Color" (2022), <https://aspe.hhs.gov/reports/substance-use-social-needs-people-color>.

²⁴⁷ 82 FR 6052, 6078.

²⁴⁸ "Under HIPAA, may an individual request that a covered entity restrict how it uses or discloses that individual's protected health information (PHI)?" *supra* note 245; U.S. Dep't of Health and Human Servs., "Uses and Disclosures for Treatment, Payment, and Health Care Operations" (Apr. 3, 2003), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html>.

building trust with the patient but urged HHS to adopt a reasonable or as practicable a standard as possible when adopting this proposal. Some patient requests may not be feasible, and a part 2 program should not have to comply with requests that are overly burdensome or impractical.

Response

We draw attention to the Sense of Congress expressed in the CARES Act that “[c]overed entities should make every reasonable effort to the extent feasible to comply with a patient’s request for a restriction regarding such use or disclosure,”²⁴⁹ and we encourage part 2 programs to do so as well. We believe that this language makes it clear that reasonable effort is expected and that it may be balanced by what is feasible. We believe that a program should not condition treatment on a TPO consent unless it has some capacity to fulfill patients’ requests for restrictions on uses and disclosures for TPO such that “every reasonable effort” has some meaning. We are finalizing as proposed in § 2.22 a requirement to include in the Patient Notice a statement that the patient has the right to request restrictions on disclosures for TPO and in § 2.26 a patient’s right to request restrictions.

Comment

With respect to proposed § 2.26(a)(4), a health system suggested that a request to restrict access to records for treatment purposes would likely not be granted since such a restriction could not be reasonably guaranteed in an EHR. In its system, part 2 programs have been implemented as restricted departments. Access controls have been implemented to permit emergency physicians to access such records by breaking the glass and documenting the purpose of access. At this time, the commenter believed that there is not a practical way to operationalize the inclusion of additional language in the break the glass process so emergency physicians could view language to not further use or disclose this information.

Response

As finalized § 2.26(a)(4) states that “[i]f information from a restricted record is disclosed to a health care provider for emergency treatment under paragraph (a)(3) of this section, the part 2 program must request that such health care provider not further use or disclose the information.” Section 2.26(a)(3) permits use of restricted records for emergency treatment. While we have stated in this

rule that data segmentation is not required, we also stated in 2017 that “data systems must be designed to ensure that the part 2 program is notified when a ‘break the glass’ disclosure occurs and part 2 records are released pursuant to a medical emergency. The notification must include all the information that the part 2 program is required to document in the patient’s records.”²⁵⁰ We recognize that EHR systems have varying degrees of functionality for implementing requested restrictions and programs are in different stages of updating their systems; however, we believe that programs need to evaluate how the limitations of their EHRs may affect patient choice and develop policies accordingly. For example, if a program conditions treatment on a patient’s TPO consent and the patient agrees to sign the consent, but only if their records are not provided to a certain provider, the program should have the means to accommodate the request and if not, allow the patient to sign a more limited consent as appropriate within the context. While lack of EHR system capability may be a valid rationale for not accommodating some patients’ requests for restrictions, it may also be a basis for not adopting a policy of conditioning treatment on signing a single consent for all TPO if the program has no other mechanism available to limit disclosures of part 2 records in the event that patients request restrictions.

Final Rule

We are finalizing this new section as proposed. We also note the Sense of Congress expressed in section 3221(k)(3) of the CARES Act stating that “[c]overed entities should make every reasonable effort to the extent feasible to comply with a patient’s request for a restriction regarding a particular use or disclosure.” We also encourage part 2 programs that are not covered entities to make such efforts. OCR has provided examples in guidance about the analogous HIPAA provision that could demonstrate “reasonable effort” to operationalize compliance with a patient’s request for a restriction including in circumstances when an individual is unable to pay for their health care in full. For instance, consistent with 45 CFR 164.522(a)(1)(vi) we cite the example that “if an individual pays for a reproductive health care visit out-of-pocket in full and requests that the covered health care provider not submit PHI about that visit in a separate claim for follow-up care to their health plan, the provider

must agree to the requested restriction.”²⁵¹ If an individual wishes to not receive fundraising communications, we noted in preamble to the 2013 Omnibus Final Rule that “[c]overed entities should consider the use of a toll-free phone number, an email address, or similar opt out mechanisms that provide individuals with simple, quick, and inexpensive ways to opt out of receiving further fundraising communications.”²⁵² For instance, a covered entity might develop a phone-based process that supports individuals in making appropriate requests for restrictions on use and disclosure of PHI.²⁵³

Some entities also have developed specific forms to facilitate compliance with 45 CFR 164.522 requirements.²⁵⁴ Similar reasonable efforts could be used to operationalize requests for restrictions in § 2.26 as finalized, such as supporting options for a patient wishing to restrict disclosures for TPO.

Section 2.31—Consent Requirements.

Section 2.31(a) Requirements for Written Consent

Proposed Rule

The Department proposed to align the required elements for a part 2 consent in paragraph (a) with the required elements of a HIPAA authorization, to include: the patient’s name; the person or class of persons making the disclosure; a description of the information to be disclosed in a specific and meaningful fashion; a designation of recipients; a description of the purpose or if no stated purpose, “at the request of the patient;” the patient’s right to revoke consent and how to do so; an expiration date or event; the patient’s or authorized person’s signature; and the date signed. In addition, the Department proposed several provisions in the consent requirements to support implementation of the CARES Act requirement to permit

²⁵¹ “Under HIPAA, may an individual request that a covered entity restrict how it uses or discloses that individual’s protected health information (PHI)?” *supra* note 245.

²⁵² 78 FR 5565, 5621 (Jan. 25, 2013).

²⁵³ See Ctrs. for Medicare & Medicaid Servs., “CMS Security and Privacy Handbooks,” <https://security.cms.gov/learn/cms-security-and-privacy-handbooks>; Ctrs. for Medicare & Medicaid Servs., “CMS Privacy Program Plan,” <https://security.cms.gov/policy-guidance/cms-privacy-program-plan>.

²⁵⁴ See Kyle Murphy, “How IHS plans to implement the HIPAA Privacy Rule,” HealthITSecurity (Jan. 11, 2013), <https://healthitsecurity.com/news/how-ihs-plans-to-implement-the-hipaa-privacy-rule> (discussing Indian Health Service efforts). See also, Indian Health Service, “Patient Forms,” <https://www.ihs.gov/forpatients/patientforms/>.

²⁴⁹ See section 3221(k)(3).

²⁵⁰ 82 FR 6052, 6096.

a single consent for all future uses and disclosures for TPO, as listed below:

- The recipient may be a class of persons including a part 2 program, covered entity, or business associate and the consent may describe the recipient as “my treating providers, health plans, third-party payers, and those helping operate this business” or use similar language. The consent also may include a named intermediary under paragraph (a)(4)(ii), as applicable.

- The statement, “for treatment, payment, and health care operations” is a sufficient description of the purpose when a patient provides consent for all future uses or disclosures for those purposes.

- The required expiration date or event may be “none” for a consent for all future uses and disclosures for TPO.

- The consent must include:
 - The statement that the patient’s record (or information contained in the record) may be redisclosed in accordance with the permissions contained in the HIPAA regulations, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.

- A statement about the potential for the records used or disclosed pursuant to the consent to be subject to redisclosure by the recipient and no longer protected by this part.

- The consequences to the patient of a refusal to sign the consent.

The Department proposed to require that a consent to disclose part 2 records to intermediaries state the name(s) of the intermediary(ies) and one of the following:

- The name(s) of member participant(s) of the intermediary; or
- A general designation of a participant(s) or class of participants, which must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being used or disclosed.

The Department proposed to remove from the consent requirements a required statement of a patient’s right to obtain a list of disclosures made by an intermediary.

Finally, the Department proposed wording changes to replace the term “individual” with the term “person” to comport with the meaning of person in the HIPAA regulations and consistent with similar changes proposed throughout this part.

Required Elements of Consent

Comment

Some commenters who supported the proposed alignment of part 2 with the

HIPAA regulations expressed enthusiasm for what they described as a long-awaited change that would support the streamlining of administrative processes, improvements in care coordination, and reduced inequities in how SUD treatment is viewed compared with general health care. One commenter specifically appreciated the clarification that electronic signatures are permitted. An Indian health board noted that allowing American Indian/American Native patients to identify a “class of participants” with a treating provider relationship (like a “health care team”) within a single prior consent would facilitate care within the Indian health system. Another supporter pointed out that including “use” as well as “disclosure” clarifies the consent form and noted that informing patients about the ability for information to be redisclosed it also important. A health information management association described the changes as “removing regulatory morass.” A health plan believed that the proposed changes “mak[e] it easier to comply with both regulatory requirements [of part 2 and the HIPAA regulations] without adding an additional layer of regulatory burden. The statutorily required six elements [of a consent] noted above as well the additional explanations for failing to sign a consent will better ensure that patients are apprised of their rights under Part 2 and instill patients’ trust.”

Response

We appreciate the comments about our efforts to improve health care and reduce burdens on regulated entities by aligning the required elements of the written consent for disclosure of part 2 records with the required elements of a HIPAA authorization to disclose PHI.

Comment

Many commenters requested clarification and simplification of the consent requirements. One commenter recommended that the Department develop model consent language, limited to a single comprehensible paragraph with an option to find further information online, such as through a scannable QR code. Some commenters stated that the part 2 consent is vague, complicated, and difficult to read and should be simplified into plain language for an ordinary person and they opposed the proposed changes to consent. They also urged the Department to “prioritize transparency.” Another commenter asserted that it is in providers’ best interests to inform patients “of their rights in a straightforward, easy-to-

understand manner, focusing on how their information will be used and who will have access to it.”

Response

We appreciate the comments recommending simplification and streamlining of the required consent and will consider the various suggestions for doing so as we develop guidance or other materials. We agree that consent should be in plain language that ordinary readers can understand and believe that the required statements can be drafted in that manner.

Comment

Several commenters believed that since the proposed part 2 consent requirements are like a HIPAA authorization, it is confusing to have similar documents with different purposes. They recommended that the consent process be easily folded into existing HIPAA compliance processes, preferably incorporating the acknowledgment of receipt of the HIPAA NPP and the patient’s part 2 consent into the same document.

Response

We appreciate the concern and believe that aligning the required elements of a part 2 consent with those required for a HIPAA authorization will facilitate the use of a single form by part 2 programs that are covered entities, and thus must meet both sets of requirements.

Comment

Several commenters suggested ceasing use of the word “consent” when referring to disclosure of records and using the term “authorization” instead.

Response

We decline to make this change because covered entities and part 2 programs, particularly those that are not covered entities, are still obligated to comply with differing sets of disclosure permissions. Moreover, 42 U.S.C. 290dd–2, as amended by the CARES Act, continues to expressly refer to consent and thus this final rule remains consistent with statutory terminology.

Although we are modifying the requirements for a part 2 consent to align more closely with a HIPAA authorization, the scope and effect of these documents continue to differ in meaningful ways. For example, a part 2 consent is required for uses and disclosures of part 2 records for TPO, but a HIPAA authorization is not required for uses and disclosures of PHI for TPO. The part 2 consent is required for part 2 programs and the

authorization is for covered entities and business associates. Because of these and other differences, we believe using the term “authorization” for individual permission under HIPAA as well as for patient permission under part 2 would create confusion.

Comment

An academic medical center suggested making no changes to part 2 consent requirements for HIPAA covered entities, but instead allowing them to use the HIPAA authorization to obtain consent for TPO and to use the patient’s right to request a restriction for more granular consents, such as for disclosure limited to a specific provider.

Response

We assume in this response that the granular consent referred to in the comment is a consent for some aspects of TPO, but not the full scope of the TPO consent. We decline to adopt this suggestion in its entirety because the HIPAA authorization applies to a narrower set of uses and disclosures than part 2 and does not have all the required elements of a part 2 consent. For example, the consent, as finalized here, requires a statement about the potential for records to be redisclosed by the recipient when they are disclosed under a TPO consent, and it contains special requirements for disclosures through an intermediary. Covered entities that are also part 2 programs will have more flexibility under the final rule consent requirements, so that they may be able to use a single form that meets the applicable requirements of a part 2 consent and a HIPAA authorization. Covered entities that are recipients of part 2 records but are not operating a part 2 program do not need to create or use a part 2 consent. Instead, covered entities that are not part 2 programs may use a HIPAA authorization to disclose part 2 records they receive provided that the authorization is not for the release of medical or other information generally. The authorization form must be specific to part 2 records or records of SUD treatment rather than “my medical records,” so that it identifies the information in a specific and meaningful fashion according to § 2.31.

Comment

In addition to supporting the proposal to allow a single consent for all future uses and disclosures for TPO, a county government recommended that programs be allowed to rely on verbal consent when making patient referrals, particularly at the initial stages of patient access to and engagement in

treatment and requested regulatory guidance on how to do so. The commenter explained the importance of verbal consent for referral or intake purposes before a treatment relationship has been established in many instances. In the alternative, the commenter suggested creating a safe harbor from part 2 violations “for providers who share information based on a verbal consent to refer a patient for treatment (which may first take place through a call center) and then later request written consent at the first appointment with the patient to share for TPO purposes.”

Response

We decline to adopt an express permission to accept a verbal consent to disclose part 2 records for purposes of intake and referral because prior written consent is a statutory requirement in 42 U.S.C. 290dd–2(b)(1)(A); however, some options for handling referrals verbally may be available depending on the circumstances. One approach would be to provide de-identified information about the patient to a potential treatment provider to determine if a placement is suitable and available and then either provide referral information to the potential patient so that they can contact the new provider independently or include the patient in a three-way call with the second provider and allow the patient to provide identifying information directly to that provider. In a medical emergency, involving an attempted overdose, or similar crisis, a program could disclose part 2 records to a hotline call center as needed to provide treatment. Similarly, in 2020 the Department amended part 2 to permit disclosures of patient information to another part 2 program or other SUD treatment provider during State or federally-declared natural and major disasters when a part 2 program is closed or unable to provide services or obtain patient informed consent.²⁵⁵

Comment

A commenter recommended that, after obtaining the original written consent, programs should be required to notify patients before each use, disclosure, and redisclosure of their part 2 records and give them the opportunity to rescind consent.

Response

This recommendation runs counter to the CARES Act requirement to allow a single consent for all future uses and disclosures for TPO. Further, we do not believe it would be practical to require

that patients be notified and given the opportunity to rescind consent before each use, disclosure, and redisclosure of their part 2 records, and it would likely create a large increase in burdens for programs and other entities subject to part 2 requirements. That said, nothing in the rule prohibits programs from notifying a patient before a particular use or disclosure of their part 2 records.

Designation of Recipients and Purpose

Comment

Several commenters recommended complete removal of the consent requirement for TPO, stating that the new disclosure permission does not go far enough to align with HIPAA.

Response

This recommendation exceeds the scope of the changes authorized under the CARES Act amendments to 42 U.S.C. 290dd–2. The CARES Act did not eliminate the statutorily mandated consent requirement for TPO uses and disclosures.

Comment

A few organizations requested clarification of whether the phrase, “people helping to operate this program,” in the general designation for a TPO consent includes case management and care coordination providers and suggested that it should.

Response

We agree with the commenters that within the part 2 context, “people helping to operate this program” could include case management and care coordination providers who are QSOs. Disclosures to case management and care coordination providers who are not QSOs would also be permitted under a TPO consent as disclosures for treatment. Regarding the TPO consent, the phrase “people helping to operate this program” is intended to cover those who are not part 2 program personnel and who would be QSOs (or business associates for part 2 programs that are covered entities).

Comment

Some commenters generally opposed the proposed change to permit a single consent for all future uses and disclosures for TPO in part because it would not require designating specific recipients.

Response

The CARES Act amended 42 U.S.C. 290dd–2 to restructure the statutory permission to disclose part 2 records with consent for TPO. Thus, the Department is required to implement

²⁵⁵ 85 FR 42986, 43018.

the consent requirements for the new disclosure and redisclosure permissions. The CARES Act amendments preserved the requirement to obtain initial consent and the prohibition against use of records in proceedings against a patient—both core elements of the part 2 confidentiality protections for SUD records. We further discuss the single TPO consent in § 2.33.

Uses and Disclosures With Written Consent

Comment

Commenters opposing use of a single TPO consent recommended that the consent provide clear options for the types of consent a patient may sign, which would include a consent for a specific, one-time use or disclosure. The commenters believed that this approach would allow patients to understand their options and to avoid being pressured into signing a TPO consent because they mistakenly believe it is their only option.

Response

We agree that part 2 programs should ensure that patients understand their consent options—which include signing a consent for a specific, one-time use or disclosure—and we encourage programs to draft their consent in a manner that is clear and easy to understand. Congress urged the Department to provide incentives to programs for explaining to patients the benefits of sharing their records.²⁵⁶ Accordingly, the manner in which programs offer information about different consent options should not undermine efforts to explain to patients the benefits of TPO consent. Sections 2.22 and 2.31(a) of this final rule require that part 2 programs notify patients of their rights and obtain consent before using and disclosing records for TPO.

Comment

Approximately half of commenters on intermediaries opposed the Department's proposal to retain consent requirements for disclosures to intermediaries that differ from consent requirements for disclosures to business associates generally. Of the HIEs and health IT vendors that commented on this set of proposals, most expressed opposition. Opposing commenters believed that the special provisions for intermediaries were a holdover from before the CARES Act and were inconsistent with aligning part 2 with the HIPAA regulations, especially with

regard to the new provision to allow a single TPO consent.

The board of supervisors for a large county explained the county's view that the combination of consent proposals (allowing TPO consent and retaining the consent provision for intermediaries) would result in a system where health plans, third-party payers, and business associates may be generally described in a consent as recipients, but these same recipient entities must be specifically named if the disclosure is made through an HIE. According to the commenter, "[t]his imposes a burden on the use of HIEs for enhancing patient care while providing no discernable privacy benefit."

A state-wide e-health collaborative that administers a network of HINs similarly remarked that if a patient signed a consent form designating "my health plan" as the recipient, the part 2 program would be permitted to disclose such information directly to the health plan, but the program would be prohibited from disclosing that information to the very same health plan if the disclosure was made via an intermediary without specifically naming the intermediary and the health plan. A large health IT vendor also voiced these concerns, describing the potential result as a "two-tiered" system that perpetuates discrimination because patients with SUD cannot reap the benefits of integrated care that is facilitated by shared electronic records.

Response

We appreciate the comments and information about how intermediaries operate and acknowledge that the CARES Act changes to consent for uses and disclosures for TPO and redisclosures by business associates have significantly reduced the need for a regulatory provision for intermediaries. In response to public comments the final rule excludes covered entities and business associates from the definition of "intermediary" in § 2.11. Thus, an HIE, for example, that meets the definition of "business associate" is excluded from the definition of "intermediary" and would not need to be specifically named in the consent—it would fall under the provision for a general designation under a TPO consent in § 2.31(a)(4). Other issues regarding intermediaries are discussed in §§ 2.11, 2.13, and 2.24.

Comment

A commenter recommended changes to § 2.31 that would modify the wording of a consent to specifically permit disclosures to the Food and Drug

Administration (FDA) even after revocation of consent.

Response

We appreciate the comment, but believe expressly permitting additional disclosures after revocation of consent, where consent is required, is inconsistent with respecting patient choice. However, there may be circumstances where consent is not required for disclosures to the FDA, for example, if they fall within the provision for program audits and financial evaluations in § 2.53 or public health disclosures of de-identified records under § 2.54.

Comment

One commenter recommended that disclosures to public health authorities be included in the general TPO consent.

Response

The CARES Act mandated that disclosures to public health authorities are permitted without consent, but this permission applies only to records that have been de-identified. Further, the general consent authorized by the CARES Act applies only to uses and disclosures for TPO. Under the HIPAA Privacy Rule, disclosures to public health authorities are not considered disclosures for TPO and we apply this same interpretation to part 2. To the extent that a patient elects to consent to the disclosure of identifiable records to a public health authority, the consent must include a specific designation of the recipient.

Consent for Fundraising and De-Identification Activities

Comment

A commenter suggested that consent for fundraising be offered as an opt-out rather than an opt-in process. Other commenters requested that fundraising not be allowed or that consent for use or disclosure of part 2 information for fundraising be obtained using a separate consent form (*i.e.*, not combined with any other consent). A few commenters stated that part 2 programs did not need to use part 2 records for fundraising purposes.

Response

Under the HIPAA Privacy Rule, fundraising falls within the definition of health care operations.²⁵⁷ The CARES Act required us to incorporate the definition of health care operations wholesale into this regulation. However, the CARES Act also included a Sense of

²⁵⁶ See sec. 3221(k)(5) of the CARES Act.

²⁵⁷ 45 CFR 164.501 (definition of "Health care operations," paragraph (6)(v)).

Congress that health care operations do not include fundraising for purposes of part 2.²⁵⁸ Thus, taking into account the Sense of Congress, a general TPO consent, without more, is not sufficient to allow the use and disclosure of records for fundraising purposes by a part 2 program that obtains a TPO consent. We considered whether to require a separate consent for an entity's fundraising activities, but determined that offering an opt-out for fundraising on the same form as consent for TPO would place appropriate guardrails on fundraising uses and disclosures consistent with the Sense of Congress without increasing burdens for part 2 programs. Part 2 programs, covered entities, and business associates that receive part 2 records under a TPO consent would be permitted to use and redisclose the records according to the HIPAA requirements. We are implementing the requirement at 42 U.S.C. 290dd–2(k)(4) to add the definition of “health care operations” to this regulation as it is defined in HIPAA, and operationalizing the Sense of Congress for fundraising purposes.

Comment

In the NPRM, we requested comment on whether the Department should require entities subject to part 2 requirements to obtain consent to use records for de-identification purposes and whether such consent should be structured to provide patients with the ability to opt-in or opt-out of having their records used in this manner. One commenter, an HIE, opined that the Department should not mandate either option because when de-identification is done appropriately through expert determination method or safe harbor method under 45 CFR 164.514(b), there is no possibility that information will be reidentified.

Response

As we explained in the NPRM, although we believe that an opt-in requirement would offer more patients more control over their records and best fulfill privacy expectations, we also believe that requiring patient consent for de-identification activities would be inconsistent with—and potentially hinder—the new permission to disclose de-identified information for public health purposes under 42 U.S.C. 290dd–2(b)(2)(D), as amended by section 3221(c) of the CARES Act. Such a requirement also would create a barrier to de-identification in a manner that

negatively affects patient privacy by increasing permissible but unnecessary uses and disclosures of identifiable part 2 records in circumstances when de-identified records would serve the intended purpose.

Implementation Concerns

Comment

One commenter recommended that the Department work with ONC and provide guidance, technical assistance, and model forms to assist regulated entities to comply with the proposed changes to consent.

Response

We will continue to work with our Federal partners, including ONC, as needed to provide guidance, technical assistance, and model forms for regulated entities.

Comment

Another commenter requested clarification of whether consent could be broadly obtained and apply to a patient's entire historical record maintained by a part 2 program.

Response

Yes, a consent may apply broadly to all future uses and disclosures for TPO and may apply to a patient's entire treatment record.

Expiration of Consent

Comment

A managed care organization requested clarification that an expiration date is not required, consistent with the HIPAA Privacy Rule.

Response

The commenter is correct in observing that an expiration date is not required under the modified consent requirements if the consent is for all future uses and disclosures for TPO. As noted in the NPRM, the Department does not intend to create substantive change by replacing “expiration date, event, or condition” with “expiration date or an expiration event that relates to the individual patient or the purpose of the use or disclosure.” However, the example proposed in § 2.31(a)(7) that allows “none” to be entered if the consent is for a use or disclosure for TPO represents a change from the current part 2 consent. Although the HIPAA Privacy Rule allows an authorization to have “none” as an expiration date or event only in limited circumstances,²⁵⁹ the ability to enter “none” for TPO consent under part 2

creates greater consistency with the HIPAA Privacy Rule because the HIPAA Privacy Rule neither requires consent nor authorization for TPO uses or disclosures.²⁶⁰ Under § 2.31(a)(7) a blank expiration date or event is insufficient, but an actual date is not always required. Other expiration language for a TPO consent that is consistent with 42 U.S.C. 290dd–2(b)(1)(C) is a phrase such as “until revoked by the patient.”

Comment

One commenter stated that the consent should not be indefinite and suggested that, at a minimum, the written consent should be renewed annually.

Response

Annual renewal of consent is not required under HIPAA, and we are not finalizing a requirement to do so under part 2. This would run counter to the permission to provide consent for all future uses and disclosures for TPO. However, we recognize that it may be valuable to periodically ensure that all patient documentation is up to date and that it may be a good practice to invite patients to review their consent choices and any documents designating surrogate decision makers, such as medical powers of attorney. We view this as a matter of good practice, rather than a legal requirement.

Conditioning Treatment on Consent

Overview of Comments

A professional association for SUD providers and 10 state affiliates as well as a major health plan/health insurer (who otherwise supported the TPO consent) opposed allowing part 2 programs to condition treatment on the signing of a single consent for all future uses and disclosures for TPO.

Comment

An SUD provider requested clarification about conditioning treatment on signing consent to disclose records and whether the Department intended the required statement about the consequences of not signing the consent to mean that part 2 programs will not have to comply with the HIPAA Privacy Rule (which generally prohibits conditioning treatment on signing an authorization).

²⁵⁸ See section 3221(k)(4) stating that paragraph (6)(v) of “health care operations” in 45 CFR 164.501 shall not apply.

²⁵⁹ 45 CFR 164.508(c)(1)(v).

²⁶⁰ U.S. Dep't of Health and Human Servs., “Guidance: Treatment, Payment, and Health Care Operations” (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html>.

Response

A part 2 program is not subject to the HIPAA Privacy Rule unless it is also a covered entity. The substantive differences between the HIPAA Privacy Rule and part 2 regarding conditioning treatment on signing a consent or authorization arise from the fact that the HIPAA Privacy Rule does not require any type of consent or authorization for TPO. Thus, the need to condition treatment, for example, on an authorization for payment disclosures, does not arise under HIPAA. However, part 2 expressly allows conditioning treatment on a consent for disclosures for payment, for example, in § 2.14 (Minor patients). And we stated in the NPRM preamble that a “Part 2 program may condition the provision of treatment on the patient’s consent to disclose information as needed, for example, to make referrals to other providers, obtain payment from a health plan (unless the patient has paid in full), or conduct quality review of services provided.” Because the prohibition on conditioning treatment on a signed authorization under HIPAA does not track closely to part 2,²⁶¹ we are adopting, as proposed, only language from paragraph (c)(2)(ii)(B) of 45 CFR 164.508, and only a modified version of the first part of that paragraph. Thus, with respect to conditioning treatment on consent, § 2.31 requires a statement of “the consequences to the patient of a refusal to sign the consent.”

Comment

Several commenters asserted that part 2 programs should not be permitted to condition treatment on a requirement that the patient sign the general TPO consent. They asserted that could create a barrier to treatment or harm patients’ privacy interests. A few of these commenters recommended that if conditioned consent was allowed the minimum necessary requirement should apply to any such disclosures.

Response

The availability of a single consent for all future uses and disclosures for TPO raises new considerations for patient confidentiality and ethical practice if access to treatment is conditioned on signing such a consent. Congress did not directly address whether a program may condition treatment on a TPO consent, but emphasized guardrails to ease

privacy concerns in section 3221 of the CARES Act. We believe that a program should not condition treatment on a TPO consent unless it has taken reasonable steps to establish a workable process to address patients’ requests for restrictions on uses and disclosures for TPO. We are finalizing as proposed in § 2.22 the rule of construction that a patient has the right to request restrictions on disclosures for TPO and in § 2.26 a patient’s right to request restrictions. Additionally, the existing rule provides that all disclosures of part 2 records should include only the information necessary for the purpose of the disclosure.

Comment

Several other commenters requested clarification of what is needed to give patients notice that treatment may be conditioned on signing consent for TPO.

Response

The regulation does not require specific language; however, consent for TPO use and disclosure should include a statement that patient consent is needed (or required) to allow the program to use and disclose the patient’s records for TPO (or “to help the program operate its health care business”) or something similar. The final rule also requires a statement or statements explaining the consequences of failing to sign, based on the program’s consent policies. For example, a program may decide not to provide ongoing treatment although it allows for an initial evaluation, or it may require payment before services are provided, or it may offer a more narrow or specific consent option. The program is not required to do so, but may find it helpful to point to the patient’s right to request restrictions on TPO disclosures and the program’s commitment to accommodate such requests. We assume that programs will carefully consider their goals, treatment population, and professional standards in deciding how to fashion a statement about conditioning treatment on signing a TPO consent. New patients are likely to be more hesitant about signing broad disclosure permissions than existing patients who have an established rapport with staff.

Final Rule

The final rule adopts all proposed modifications to § 2.31(a), but refers to “HIPAA regulations” in place of the references to 45 CFR 164.502 and 164.506. This modification aligns with the addition of the new defined term, “HIPAA regulations.”

Section 2.31(b) Consent Required: SUD Counseling Notes

In the NPRM, we requested comments on a potential definition of “SUD counseling notes” and specific consent provisions regarding these notes. We offered for consideration that a separate consent requirement, if adopted, would not apply to SUD counseling notes in certain specific situations such as when such information was required for the reporting of child abuse or neglect, needed for the program to defend itself in a legal action or other proceeding brought by the patient, or required for oversight of the originator of the SUD counseling notes.²⁶²

Overview of Comments

We received comments in support of the proposal, asking for modification, and expressing concern about consent provisions related to SUD counseling notes. We also received comments on such issues as whether a separate consent should be required for SUD counseling notes, the similarity or distinctions between psychotherapy notes under HIPAA and SUD counseling notes, and patient rights to access such notes. We respond to these comments below. Comments primarily relating to the proposed definition of “SUD counseling notes” are discussed in § 2.11.

Comment

We received support for the proposals in the NPRM concerning SUD counseling notes from commenters such as HIE/HINs, state and local agencies, and recovery organizations for treating SUD counseling notes under § 2.31 similar to psychotherapy notes in the HIPAA Privacy Rule by requiring a separate written consent for their disclosure. These commenters believed a separate consent would serve as an added layer of protection to patients receiving service under § 2.31. A medical professionals association believed that parties are already familiar with how to comply with psychotherapy notes under HIPAA. If such a category is created, the association urged the Department to issue clear guidance to make the segregation of these counseling notes as easy as possible so that part 2 programs do not have to take repetitive actions that would add to their administrative burden.

Response

We appreciate these comments and are finalizing provisions in this section that require a program to obtain separate

²⁶¹ U.S. Dep’t of Health and Human Servs., “What is the difference between ‘consent’ and ‘authorization’ under the HIPAA Privacy Rule?” (Dec. 28, 2022), <https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html>.

²⁶² See full discussion at 87 FR 74216, 74231.

consent for any use or disclosure of SUD counseling notes subject to certain specific listed exceptions. We will consider what additional guidance may be helpful on these issues after the rule is finalized.

Comment

According to several SUD and recovery associations, notes often contain highly sensitive information that supports therapy. Limiting access to these notes is critical to protect the therapeutic alliance due to the unique risks that patients face due to the risks of inappropriate sharing of highly sensitive information in these notes. A health care provider believed the SUD counseling note provision would allow a SUD provider the ability to more accurately capture critical impressions of his or her patient without running the risk that it could adversely impact the patient or the provider-patient relationship.

A few HIE associations commented that providers rarely use the option to keep psychotherapy notes as defined in the HIPAA regulations; instead, the type of information previously envisioned to be included in the psychotherapy note is now included in “progress notes” or the information is not captured and documented in an EHR. If organizations move towards utilizing a separate category for SUD counseling notes, it could lead to information either not being documented, or to important information not being captured at all, which is against the principles of interoperability supported by these associations and the Federal Government, these commenters asserted. A hospital said that in its experience clinicians, both internal and external to its organization, usually refer to these types of notes as “process notes” which are not part of the designated record set and are not documented in the EHR. This commenter also has heard from clinicians that these types of notes are rarely used.

A medical professionals association believed that SUD counseling notes should be separated from the rest of the patient’s health record, to allow a firewall between notes used by the individual therapist or treating professional and the rest of the patient’s health record (such as diagnosis, functional status, treatment plan, symptoms, prognosis, start and stop times, modalities and frequencies of treatment, medication prescription and monitoring, and results of clinical tests) that is designed to be shared, as appropriate, with other health care entities. According to this association,

psychotherapy notes provide a vital tool for psychologists to protect sensitive therapy details from third parties. These notes are a way for psychologists to protect patient privacy as to sensitive details that are important for the psychologist to remember, but that do not need to be shared with other health care entities.

Response

We discuss our changes to the definition of “SUD counseling notes” in § 2.11 above. We intend for SUD counseling note provisions in 42 CFR part 2 to parallel the HIPAA psychotherapy note provisions.²⁶³

Providers may vary in their use of SUD counseling or psychotherapy notes. Moreover, some providers in behavioral health or other medical practices also may use “open notes” intended to permit patient access to EHRs, including provider notes.²⁶⁴ The preamble to the 2000 HIPAA Privacy Rule explained that “process notes capture the therapist’s impressions about the patient, contain details of the psychotherapy conversation considered to be inappropriate for the medical record, and are used by the provider for future sessions.” The preamble further noted that “[w]e were told that process notes are often kept separate to limit access, even in an electronic record system, because they contain sensitive information relevant to no one other than the treating provider. These separate ‘process note’ are what we are calling ‘psychotherapy notes.’”²⁶⁵ By contrast, progress notes (referred to as “progress to date” in our definition of “SUD counseling notes”) would be included in the patient’s medical record or part 2 record.

We also believe that licensed part 2 program providers that are especially trained in the handling of these types of records (*i.e.*, familiar with and qualified to maintain separate session notes) will likely be able to understand and apply special requirements to protect these types of notes. We also reiterate from the NPRM that “[i]f SUD treatment is provided by a mental health professional that is a Part 2 program and a covered entity, and the provider creates notes of counseling sessions that are kept separate from the individual’s

medical record, those notes would be [considered] psychotherapy notes as well as Part 2 records.”²⁶⁶

Comment

A health IT vendor was not opposed to the proposal to create special protections for SUD counseling notes but urged the Department to develop guidance for effective implementation. Also, although it seems reasonable to this commenter to align the SUD counseling note consent requirements to the HIPAA psychotherapy note consent requirements, any requirement for “a separate written consent that is not combined with a consent to disclose any other type of health information” could be burdensome for providers who provide services to dually diagnosed (mental health and SUD) consumers.

Response

We are finalizing a modification to permit consent for use and disclosure of SUD counseling notes to be combined with another consent for use and disclosure of SUD counseling notes. Combining a consent for disclosure of SUD counseling notes with an authorization for the use and disclosure of psychotherapy notes is not permitted under the HIPAA Privacy Rule. Further, we are not aware that psychotherapy notes or SUD counseling notes are disclosed with such frequency as to create a burden for providers.

Comment

A medical professional association interpreted the NPRM to suggest that SUD counseling notes, like psychotherapy notes, would generally not be accessible to patients. The association said that in most states, patients have full or only slightly limited access to these notes. The reason is that HIPAA’s preemption requirement gives priority to state laws that give patients greater access to their records. Since most state laws on access to mental health records do not contain an exemption for psychotherapy notes, those laws are not preempted by the HIPAA provision denying patients access to psychotherapy notes. The association believed that the main exception to this effect is in the minority of states that have changed their patient access laws to align with HIPAA, including the exclusion of psychotherapy notes from the patient’s right to access their mental health records. The association anticipated that the creation of SUD counseling notes would have a similar effect on patient access except to the extent that state

²⁶³ As discussed elsewhere in this rule, psychotherapy notes are part of the designated record set. See “Individuals’ Right under HIPAA to Access their Health Information 45 CFR 164.524,” *supra* note 159.

²⁶⁴ See Steve O’Neill, Charlotte Blease, Tom Delbanco, “Open Notes Become Law: A Challenge for Mental Health Practice,” *Psychiatric Services* (2021), <https://pubmed.ncbi.nlm.nih.gov/33971748/>.

²⁶⁵ 65 FR 82461, 82623.

²⁶⁶ 87 FR 74216, 74230.

laws on patient access to records exclude, or are otherwise different for, SUD records.

Response

Under the HIPAA Privacy Rule, patients do not have a right of access to psychotherapy notes.²⁶⁷ We have noted that while there is no right of access to psychotherapy notes, “HIPAA generally gives providers discretion to disclose the individual’s own protected health information (including psychotherapy notes) directly to the individual or the individual’s personal representative.”²⁶⁸ Under HIPAA, psychotherapy notes must be maintained separately from the rest of the individual’s medical record. We establish a similar expectation with respect to SUD counseling notes in this final rule.

Under the existing (and final) rule, part 2 programs are vested with discretion about providing patients with access to their records. Section 2.23 neither prohibits giving patients access nor requires it and a part 2 program is not required to obtain a patient’s written consent or other authorization to provide such access to the patient. We confirm here that SUD counseling notes fall within the scope of part 2 records although they are separated from the rest of the patient’s SUD and medical record under § 2.11 (SUD counseling notes). The final rule therefore does not require under § 2.23 that SUD counseling notes be disclosed to the patient, but a clinician may choose to do so voluntarily.

We assume that SUD treating professionals are aware of the statutory and regulatory requirements in their state pertaining to patient access to records, including access to separately maintained notes of counseling sessions, and considered state requirements when making decisions about whether to adopt the use of the SUD counseling notes provision in this final rule.

Comment

A medical professional association commented that since SUDs are frequently a dual diagnosis with mental health disorders, it is appropriate for SUD counseling notes to be like psychotherapy notes. This approach would lessen the provider’s burden

when treating dual diagnoses by requiring the same type of notes.

The association described its concerns, however, that a separate consent requirement, if adopted, not apply to training programs in which students, trainees, or practitioners use to improve their skills in a SUD treatment environment. The commenter requested that we consider patient consent for educational training using audio or video recordings. Another professional association echoed support for allowing use or disclose of SUD counseling notes for a program’s supervised student training activities.

Response

The final rule expressly provides an exception from requirements for consent to disclose SUD counseling notes when such use or disclosure is made “by the part 2 program for its own training programs in which students, trainees, or practitioners in SUD treatment or mental health learn under supervision to practice or improve their skills in group, joint, family, or individual SUD counseling.” This parallels the exception for psychotherapy notes in the HIPAA Privacy Rule for training of mental health professionals. With respect to audio or video recording, the definition of “SUD counseling notes,” like the definition of “psychotherapy notes” under HIPAA, does not include such recordings.

Comment

We received many comments on segregation or separation of SUD counseling notes from other parts of a patient’s medical record. A medical professionals association recommended that SUD counseling notes be handled in the same manner that psychotherapy notes are treated under HIPAA. This category would provide greater protection for SUD counseling notes and limit the notes from being shared under a TPO consent. Providers are already familiar with how to comply with psychotherapy notes under HIPAA. If such a category is created, the association encouraged the Department to issue clear guidance to make the segregation of these counseling notes as easy as possible so that part 2 programs do not have to take repetitive actions that will add administrative burden.

A medical school trade association echoed these comments stating that it supports not disclosing SUD counseling session notes without a separate written authorization or consent. These notes, which are maintained primarily for use by the originator of the notes, should have heightened protections and accountability. This policy would be

consistent with the approach that limits the individual’s right of access to psychotherapy notes under HIPAA. The association requested HHS explore, in partnership with stakeholders, how these SUD counseling session notes would be best protected while minimizing data segmentation challenges. The association also asked that the Department issue guidance on how these counseling notes could be segregated.

A health IT vendor indicated that it understands the importance of maintaining the confidentiality of counseling sessions and supports maintaining strict protections for counseling session notes. Its platform enables providers to maintain these notes as strictly confidential.

A few professional associations and an individual commenter asserted that segregation of client notes under this section creates an extra burden, which is harder for publicly funded without money for the systems.

According to a medical professionals’ association, the creation of a distinct class of psychotherapy notes in HIPAA provides an illustrative example of the challenge of implementing specific data protections within a medical record: options for segregating SUD records from other records that require manual or duplicative action by the clinician are likely not viable at scale. Further, the personnel time and infrastructure costs of configuring such an option in the EHR is not negligible.

A county department believed that SUD counseling notes are appropriate to share with the patient upon request. The agency asserted that it would be inadvisable to segregate these notes from the remainder of the medical record, and that it would add undue burden to subject them to a separate patient consent requirement.

An academic medical center stated that even if SUD counseling notes were included in the final rule, it did not anticipate using them. Segregating a progress note would be administratively burdensome to do. Additionally, segregation of information impacts the overall care of the patient by not providing quality continuity of care to patients being treated in SUD programs, according to this commenter. The commenter added, allowing all SUD progress notes related to a patient’s care to be accessible and integrated in the EHR would allow the medical team to view and use notes from the patient’s SUD course of treatment to care for the patient.

A health insurer asserted that segregation of SUD notes could impede the sharing of information that should

²⁶⁷ See 65 FR 82461, 82554; 45 CFR 164.524(a)(1)(i).

²⁶⁸ See U.S. Dep’t of Health and Human Servs., “Information Related to Mental and Behavioral Health, including Opioid Overdose” (Dec. 23, 2022), <https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html>.

be part of the patient's overall part 2 record and information that is critical to support necessary treatment and care coordination. In addition, the commenter stated that such segregation and the attendant requirements attached to these notes (e.g., separate consent required for release) would unduly burden patients, providers, and other stakeholders with no demonstrated justification or value. The commenter requested that, if the Department created a separate category of record information for "SUD counseling notes," the final rule clarify that this narrow category is limited to contemporaneous notes from an in-person counseling session and not, as was noted in the proposed rule, summary information from the overall part 2 record and information such as diagnosis, treatment plan, progress notes, etc.

Response

We appreciate comments concerning the potential challenges of maintaining SUD counseling notes apart from the medical or part 2 record. "SUD counseling notes" as defined in this rule "are separated from the rest of the patient's SUD and medical record." Although the definition is neutral regarding the format in which SUD counseling notes are maintained, a key aspect is that they are not generally available to anyone other than the treating clinician. Thus, session notes of an SUD provider that are maintained in an EHR environment where they are accessible by multiple members of the treatment team would not qualify as SUD counseling notes nor receive the additional protection from disclosure.

The final rule's approach to SUD counseling notes and requiring that such notes be separate from other portions of the record is entirely consistent with the long-standing approach regarding psychotherapy notes within HIPAA which dates back to 2000. In the 2000 HIPAA Privacy Rule, we explained that "any notes that are routinely shared with others, whether as part of the medical record or otherwise, are, by definition, not psychotherapy notes, as we have defined them. To qualify for the definition and the increased protection, the notes must be created and maintained for the use of the provider who created them . . . [.]"²⁶⁹

We further elaborated that "[t]he final rule retains the policy that psychotherapy notes be separated from the remainder of the medical record to receive additional protection." We

noted that mental health providers told the Department that "information that is critical to the treatment of individuals is normally maintained in the medical record and that psychotherapy notes are used by the provider who created them and rarely for other purposes." Similarly, SUD counseling notes support provider recollections of sessions with the patient but are not intended to supplant other information, such as the patient's test results and diagnosis, within the part 2 record or medical record.

Comment

Several commenters raised concerns about SUD counseling notes being distinct from psychotherapy notes under HIPAA. One commenter did not believe these SUD counseling notes with additional protections promote access and exchange of valuable information and prefers an approach that destigmatizes SUD treatment and promotes access to clinically relevant information which is valuable and informative for all TPO purposes.

A state agency believed that SUD counseling notes are qualitatively different than psychotherapy notes and are most frequently maintained by unlicensed providers. The agency is concerned that this change would create additional administrative complexity and compliance challenges for part 2 programs and may have unintended consequences by restricting patient access to, or disclosure of, a significant segment of their SUD treatment records. This change seems unlikely to facilitate information exchange for care coordination purposes, and as such would seem to be inconsistent with many of the other proposed amendments, according to this commenter.

One county health department asserted that the utility of this category of records is likely minimal, and another said that requiring separate consent for SUD counseling notes would counteract the aim of facilitating greater information exchange, with unclear benefits. HHS' proposed consent framework for part 2 records provides patients with sufficient control to limit what substance use treatment information is shared and does not require creation of a category of "SUD counseling notes" with different protections.

A health care provider recommended a different approach whereby all part 2 data is used in a similar manner to psychotherapy notes. This policy would reduce the need for new part 2 workflows and interoperability frameworks. Additionally, by deeming

part 2 information identical to a psychotherapy note, that data could also be carved out of the definition of "electronic health information" and would not be subject to the 21st Century Cures Act, but still maintain critical clinical information. For example, results of clinical tests, summaries of diagnosis, functionality status, treatment plan, symptoms, prognosis and progress to date are all excluded from a psychotherapy note. By treating part 2 data or SUD data similar to psychotherapy notes, the most sensitive information made available in a part 2 encounter would continue to be restricted but critical information for treatment and continuity of care would remain available.

A health care provider commented that it did not recommend including special protection for SUD counseling notes by requiring a separate written consent for their disclosure because they are concerned that it would impede care coordination. SUD counseling notes may contain clinically relevant information and be useful to inform coordinated treatment plans. Also, given the variety of part 2 program structures, as well as differences in state licensing laws, the categorization of personnel who could create or view counseling notes would be confusing to implement and would require significant administrative burden to designate records within the SUD counseling notes category. As a result, the commenter believed that some programs may have difficulty implementing the requirement and be deterred from sharing vital information within the record for TPO purposes.

Response

Use of the SUD counseling notes provision by an SUD professional is voluntary and optional, although a program may adopt a facility-wide policy that either supports or disallows the creation and maintenance of such notes. Also, SUD counseling notes are a subset of a part 2 record and the separate consent requirement would only apply to such notes when they are maintained separately from the rest of the part 2 record. Additionally, the CARES Act, while supporting alignment of HIPAA and part 2, continues to recognize the importance of applying additional protections to SUD information. Accordingly, the Department cannot treat psychotherapy notes and SUD counseling notes as synonymous as this would be contrary to the CARES Act and 42 U.S.C. 290dd-2 as amended. Regarding requests for additional guidance, we may provide

²⁶⁹ 65 FR 82461, 82623.

additional guidance on these issues after the rule is finalized.

Comment

An academic health center said that as proposed, an SUD counseling note, created by and used by the creating provider, segments patient care and could introduce patient safety risks. Information known to only one member of the treatment team is antithetical to an integrated care approach. The commenter believed that once the patient has provided consent to be treated in our SUD program those records should be visible to the rest of the care team across the covered entity, not just the SUD treatment counselor who created the note or the SUD team.

Response

“SUD counseling notes” as defined in this rule “excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.” SUD counseling notes are intended, like psychotherapy notes, to support an individual provider and are not routinely shared with others. Information critical to patient diagnosis and treatment such as prognosis and test results, should be within the patient’s medical record or part 2 record. We do not believe the use of separate SUD counseling notes will impede either integrated care or patient safety; however, a program may adopt its own policy with respect to the use by its clinicians of such notes.

Comment

According to a health IT vendor, the treatment of SUD counseling notes under part 2 raises complexities similar to HIPAA with respect to limits on patient access and for the need for a distinct specific consent from the patient. Addressing such matters depends on whether the notes are included in a specific medical record document or record type or comingled with other documentation. The health IT vendor stated that many part 2 providers have not been in a habit of maintaining distinct forms of documents or records that would allow for these provisions to be so simply applied. The commenter urged the Department develop guidance for their effective implementation. The commenter suggested a single consent option to cover both psychotherapy and SUD counseling notes, not combined with any consent to disclose any other

type of health information, to facilitate the release of notes for dually diagnosed consumers being treated by the same provider/provider group. For this and other reasons, it would seem beneficial to this commenter to align these consent requirements as closely as possible to avoid confusion, and variations in data exchange rules.

Response

As noted, the Department, including ONC, is working to support implementation of EHRs and health IT within the behavioral health sector. We believe that separate consent for release of SUD counseling notes is important because these notes will be maintained distinctly from other parts of the patient’s medical record. This approach is consistent with our approach to psychotherapy notes under HIPAA.²⁷⁰ According to SAMHSA’s National Survey on Drug Use and Health, we know that many patients will have both mental health and SUDs as well as other comorbidities or co-occurring conditions. We believe the definition of “SUD counseling notes” in this final rule and the consent provisions will support integration of care and care coordination for dually diagnosed SUD and mental health patients.²⁷¹

Comment

An insurer suggested that the final rule make clear that this narrow category of SUD counseling notes is limited to contemporaneous notes from an in-person counseling session and not, as is noted in the proposed rule, summary information from the overall part 2 record and information such as diagnosis, treatment plan, and progress notes. The commenter asserted that in practice the HIPAA Privacy Rule’s provision on “psychotherapy notes” has been used by some parties as a justification for information blocking and refusal to provide information for TPO in some cases. The commenter believed that similar behavior could occur with this provision if boundaries and limitations are not clearly articulated both in the definition and related provisions of the final rule.

²⁷⁰ See “Does HIPAA provide extra protections for mental health information compared with other health information?” *supra* note 157.

²⁷¹ See Substance Abuse and Mental Health Servs. Admin., “SAMHSA Announces National Survey on Drug Use and Health (NSDUH) Results Detailing Mental Illness and Substance Use Levels in 2021” (Jan. 4, 2023), <https://www.samhsa.gov/newsroom/press-announcements/20230104/samhsa-announces-nsduh-results-detailing-mental-illness-substance-use-levels-2021>.

Response

The Department is collaborating to ensure successful implementation of information blocking requirements and acknowledges this commenter’s concerns.²⁷² That said, we believe the final definition of “SUD counseling notes” makes clear that for the purposes of part 2 SUD counseling notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Comment

An HIE/HIN stated its view that adding an additional level of complexity in the consent process is likely to cause confusion and have the practical result of eliminating data sharing in circumstances where Congress intended to facilitate the sharing of data. Should the Department decide to add such a definition, the commenter asked that HHS not prohibit a consent permitting the release of such notes from being combined with a general consent to release part 2 records. The commenter believed that any heightened security requirements could be met by requiring that a consent for release of SUD counseling notes to explicitly reference such notes in conspicuous language separate and apart from any other permissions to disclose data.

Response

As noted, consistent with the Department’s approach to psychotherapy notes in HIPAA, we are requiring a separate consent for disclosure of SUD counseling notes and specifically prohibiting combining a consent for disclosure of SUD counseling notes with a consent for disclosure of any other type of health information other than for release of psychotherapy notes. A part 2 consent form may have a combination of options, including a check box for SUD counseling notes. However, when a patient is consenting for SUD counseling notes that is the only type of information that can be indicated on the consent (other than psychotherapy notes). For instance, if a patient checks both “billing information” and “SUD counseling notes” this consent is not valid to release the SUD notes.

²⁷² See “Information Blocking,” *supra* note 160.

Comment

With respect to the proposed exception for disclosure of SUD counseling notes to lessen a serious and imminent threat to the health or safety of a person or the public, an individual commenter said that this proposed language reflecting this otherwise known as *Tarasoff*²⁷³ exception is too broad.²⁷⁴

The commenter stated the objective in this exception is to “lessen” a serious and imminent threat to the health or safety of a person or the public. The commenter believed that this approach was discriminatory because it equated being in treatment for SUD with being an imminent threat from a physical or health perspective. Specifically, the commenter said inclusion of the term “health” was too vague and suggested that if a person in SUD treatment has HIV, hepatitis B or C, or any other communicable disease, that it is the responsibility of the SUD counselor to determine whether to report that information if the patient is in a conjugal relationship or might expose another person. The commenter argued that it is sufficient to characterize the nature of the imminent physical threat, assert that the reporter has reason to believe that the imminent physical threat is serious, and any personal information that would allow a person to avoid the instigator of the threat or to allow a person(s) reasonably able to prevent or lessen the threat.

Response

We acknowledge the commenter’s concerns about the suggested exception, which we decline to include in the final rule. HIPAA and part 2 provisions on serious and imminent threats and disclosure differ. With respect to preventing harm, the final rule permits use or disclosure of SUD counseling notes under § 2.63(a)(1) and (2) based on a court order to disclose “confidential communications” made by a patient to a part 2 program when necessary to protect against an existing threat to life or of serious bodily injury, or in connection with the investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily

injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect. When such a use or disclosure is made, § 2.13 provides that “[a]ny use or disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the use or disclosure.” Thus, the information shared under these circumstances or with respect to any disclosure without consent should be the minimum necessary to carry out the purposes of the disclosure.²⁷⁵

Final Rule

As noted, we have finalized a definition of “SUD counseling notes” discussed above in section § 2.11. With respect to consent for use and disclosure of SUD counseling notes we are finalizing the provision as § 2.31(b). The consent requirement does not apply to SUD counseling notes in certain specific situations such as the: (1) use by the originator of the SUD counseling notes for treatment; (2) use or disclosure by the program for its own training programs; or (3) use or disclosure by the program to defend itself in a legal action or other proceeding brought by the patient.

Section 2.31(c) Expired, Deficient, or False Consent

Proposed Rule

The NPRM proposed in paragraph (c)(4) of this section to replace the phrase “individual or entity” with the term “person” to comport with the meaning of person in the HIPAA regulations and as consistent with similar changes proposed throughout this part. The revised language would read, “[a] disclosure may not be made on the basis of a consent which . . . [i]s known, or through reasonable diligence could be known, by the person holding the records to be materially false.” Additionally, the Department solicited comments on whether the final rule should require part 2 programs to inform an HIE when a patient revokes consent for TPO so that additional uses and disclosures by the HIE would not be imputed to the programs that have disclosed part 2 records to the HIE.

False or “Uninformed” Consent

Comment

Several commenters said that the rule should require that programs engage in an “informed consent” process where they explain the nature of the consent and potential consequences to the

patient. These commenters urged the Department to adopt an informed consent process.

Response

“Informed consent” generally refers to consent to receive treatment or consent to participate in research.²⁷⁶ As such, the obligation to ensure that patient consent is informed is outside of the scope of part 2, but is addressed in other law and is part of the professional and ethical requirements for licensed SUD professionals. However, we expect programs to ensure that consent is knowing and voluntary in the sense that the patient understands the consequences of signing or not signing the consent or authorization or that a personal representative provides consent when needed. We believe that consent that has been coerced or unknowing would be invalid and that, in the context of an application for a part 2 court order, the court would decide such matters. In addition, we believe that a consent that is based on false information or a lack of material information about the nature of the disclosure would be considered an invalid consent, as would any consent if the part 2 program knows or has reason to know that the signature was forged.

Revocation of Consent

Comment

Some commenters addressed revocation of consent for use and disclosure of part 2 records, including several member organizations of an HIE/HIN that co-signed a comment letter. Some of these commenters urged that the final rule expressly state that disclosed part 2 records cannot be pulled back from the recipient once released, following a patient’s revocation of the original signed consent as stated in the NPRM preamble discussion.

²⁷⁶ See Off. of Human Research Protections, “Informed Consent FAQs” (Sept. 24, 2003), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html> (discussing the HHS Common Rule and other requirements); Food and Drug Admin., “Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors,” (August 2023) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent>; American Medical Ass’n, Code of Medical Ethics. Chapter 2, Informed Consent, Opinion 2.1.1, <https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent>; R. Walker, TK Logan, JJ Clark et. al. Informed consent to undergo treatment for substance abuse: a recommended approach. 29 J Subst Abuse Treat. 241–51 (2005); Johns Hopkins Medicine, Off. of Human Subjects Research, “Relevant State Law Requirements” (August 2020), <https://www.hopkinsmedicine.org/institutional-review-board/guidelines-policies/guidelines/marylandlaw>. See also, e.g., 42 CFR 482.24(c)(4)(v)).

²⁷³ *Tarasoff v. Regents of the Univ. of Cal.*, 17 Cal. 3d 425 (Cal. 1976).

²⁷⁴ For an analysis of how this applies under HIPAA, see U.S. Dep’t of Health and Human Servs., “If a doctor believes that a patient might hurt himself or herself or someone else, is it the duty of the provider to notify the family or law enforcement authorities?” (Sept. 12, 2017), <https://www.hhs.gov/hipaa/for-professionals/faq/2098/if-doctor-believes-patient-might-hurt-himself-or-herself-or-someone-else-it-duty-provider.html>.

²⁷⁵ See 83 FR 239, 244; 85 FR 42986, 43003.

Response

We appreciate the comments and information provided about the consent revocation process, particularly when it occurs in an HIE environment. We reaffirm the statement in the NPRM preamble that revocation does not require pulling back records that have been disclosed and do not believe it is necessary to so state in regulatory text.

Comment

Several commenters recommended that HIEs be informed when a patient revokes consent, including an HIE association, health IT vendors, and a state government agency. One health IT vendor explained that consent revocation mechanisms may be implemented through the Trusted Exchange Framework when made by HIEs and HINs. The vendor asserted that most HIEs already receive notice of revocation when they use a model of exchange in which a potential recipient seeks medical records from another exchange participant and the current status of a patient's consent permission to have their records exchanged is known, including whether a patient has revoked consent. A health plan requested that recipients should be notified so they can stop redisclosing information they already received based on consent.

One commenter asserted that the existing pathways for complying with a more granular consent (*e.g.*, that is specific to a certain recipient or purpose) should remain available and that HIEs should be informed about changes to consent for disclosures made through the HIE. This commenter recommended that the Department explore further how HIEs learn of the consent status, whether it means that the HIE must directly record the status of a revocation or if the HIE relies on some kind of electronic "polling" of the part 2 program to ascertain if a valid consent remains or has been revoked.

In contrast, a behavioral health network/HIE opposed requiring notice of revocation to an HIE, opining that it is not necessary because—under the CARES Act—once part 2 records are disclosed to a covered entity or business associate they are no longer part 2 records. As such, the commenter stated, the records can be redisclosed without limitation under part 2 even after a part 2 consent to disclose has been revoked.

Response

We appreciate these comments, which provided perspectives on how consent and revocation are communicated through an electronic health exchange.

We disagree with the view that once records are disclosed they are no longer part 2 records. Once received by a covered entity or business associate, the part 2 records are also PHI but, under this final rule, do not have to be segregated or segmented from other PHI. However, the records remain subject to the part 2 prohibitions against uses and disclosures for certain proceedings against a patient without written consent or a court order under this part. We agree that programs should convey to recipients when a consent is provided and, where feasible, when it has been revoked. This effort should include using whatever tools are at the disposal of the program to ensure that only consented information is exchanged.

While we appreciate the comments stating that HIEs are able to operationalize a requirement to provide notice of revocation, we are concerned about the burdens that would apply to all programs if we imposed a requirement that programs "must" notify recipients upon consent revocation. Thus, while we are finalizing additional requirements for a copy of consent to travel with each disclosure of records for which consent is required, we decline to adopt a requirement for programs to notify recipients of records of each revocation. The new requirement to attach a copy of consent is discussed under § 2.32 (Notice and copy of consent to accompany disclosure). Regarding revocation, we intend for programs to convey to recipients when a patient has provided written revocation where feasible. When the records have been disclosed through an HIE, the mechanism for informing recipients of a revocation would likely depend on the consent model used by the HIE. But our expectation is that all programs make efforts to initiate actions needed to accomplish the notification and to give full effect to the patient right to revoke consent as stated in the Patient Notice.

Consistent with the recommendation of one commenter to explore further how HIEs learn of the consent status, we intend to monitor how provision of notice of revocation could work across all types of entities, including in a fully electronic environment such as an HIE, but also for stand-alone systems and paper-based exchanges.

Comment

A health information association recommended requiring programs to inform HIEs, and HIEs to follow, a patient's request to revoke consent for distribution of their information for TPO. If patients are not able to stop the exchange of their information once it is

released to an HIE, they may hesitate to consent to information being released to an HIE or HIN. If a patient's data is out of date at one provider and the patient cannot revoke consent for that information to be exchanged by an HIE, then they will continue to fight a losing battle to ensure every subsequent record is correct as the HIE may still be exchanging the incorrect information.

Response

The language in the final rule for § 2.31(a)(6) regarding "[t]he patient's right to revoke the consent in writing, except to the extent that the part 2 program, or other lawful holder of patient identifying information that is permitted to make the disclosure, has already acted in reliance on it [. . .]" is broadly applicable and therefore would include HIEs/HINs. As a result, when an HIE/HIN learns of a patient's revocation of consent they would need to cease using or redisclosing the patient's part 2 record to other entities.

Comment

An academic medical center compared the proposed part 2 TPO consent to a HIPAA authorization for TPO disclosures and explained that during the entire period that the HIPAA Privacy Rule has been effective they were not aware of any patient that sought to revoke a HIPAA authorization for use of their PHI for purposes of TPO.

Response

We acknowledge the similarities and differences between part 2 consent and HIPAA authorization. Under HIPAA, neither consent nor authorization is required for TPO, so the opportunity to revoke such an authorization is unlikely to exist. Revocation of consent is further discussed under § 2.31.

Comment

Some commenters addressed the question of whether a revocation should halt all future uses and disclosures by a recipient or whether a revocation should only prevent any further disclosures to that recipient. Commenters did not show a strong consensus on one approach, although more comments than not supported allowing additional redisclosures following revocation when the information is limited to records already in possession of the initial recipient. HIE-related comments uniformly affirmed the Department's statement in the NPRM preamble that information did not need to be "clawed back" following a revocation and several further asserted that an HIE needs to cease making redisclosures of health

information it retains once it learns of a revocation of consent or HIPAA authorization. These commenters also urged express clarification that revocation of consent only applies going forward. Commenters that supported the ability to continue making redisclosures of information retained by the recipient requested clarification to reduce concerns by part 2 programs that they could be liable for redisclosures made by recipients after consent has been revoked. As described in the discussion of § 2.13 above, a few HIE/HINs proposed addressing revocation in § 2.13 and limiting it to new information received after the revocation and to allow continued use and disclosure of part 2 records the recipient has receiving prior to the revocation.

Response

As stated in the NPRM, the Department does not expect a part 2 program to “pull back” records that it has disclosed under a valid consent based on a patient’s revocation of consent. At a minimum we intend that a written revocation serves to prohibit a part 2 program from making further uses and disclosures of a patient’s record according to the scope of the revocation. Based on the public comments received, we also intend that when records have been transmitted through an HIE, the HIE should cease making further disclosures of the patient’s record to other member participants. As stated in the NPRM, to fully accomplish the aims of the right to revoke consent, we expect that part 2 programs will work to ensure that any ongoing or automatic disclosure mechanisms are halted upon receipt of a request for revocation.

Certain recipients under a consent for TPO (part 2 programs, covered entities, and business associates) are permitted to redisclose records according to the HIPAA regulations. Under 45 CFR 164.508(b)(5) a covered entity or business associate is required to cease making further uses and disclosures of PHI received once they are informed of an authorization revocation, except to the extent they have already taken action in reliance on the authorization or if it was obtained as a condition of obtaining insurance coverage and other law provides the insurer with the right to contest a claim. We believe this requirement applies equally to revocation of a part 2 consent. This interpretation is revised from the NPRM preamble discussion that proposed a revocation would only be effective to prohibit further disclosures by a program and would not prevent a recipient part 2 program, covered entity, or business associate from using the

record for TPO, or redisclosing the record as permitted by the HIPAA Privacy Rule.

Taking into account covered entities’ obligations under HIPAA once they are informed of a revocation, we believe they are also obligated to comply with a revoked consent about which they are aware. We do not see a reason for a recipient covered entity to treat a patient’s revocation of part 2 consent differently than a revoked HIPAA authorization. For example, if a part 2 program disclosed part 2 records under a TPO consent to a health plan and the patient later revoked said consent, the health plan that is processing a claim may complete the transaction but may not process new part 2 claims for that patient/plan member. In another example, a covered entity health care provider who is currently treating a patient and has received a patient’s part 2 records will necessarily need to continue relying on the records it received to continue treating the patient (e.g., the provider cannot “unlearn” the patient’s history); however, it is prohibited from redisclosing the records once the patient revokes consent in writing. Handling revoked authorizations is not a new process for covered entities and they should therefore be capable of handling revoked consents in the same manner.

Comment

An academic medical center expressed concern about scenarios in which the part 2 program relied on the original consent for a specific use or disclosure, but such use or disclosure may need to occur after such revocation has occurred. Examples include when a patient signs a consent to permit the part 2 program to disclose records for payment purposes, to ensure the program receives appropriate reimbursement for its services but then revokes his or her consent prior to the part 2 program submitting the bill to the patient’s payor. According to this commenter, the NPRM seems to suggest that the part 2 program would no longer be permitted to make such a disclosure, despite the fact that the part 2 program agreed to treat the patient on the condition of receiving reimbursement from the patient’s payor.

Response

If a disclosure cannot practically or feasibly be stopped after revocation because it is already in process or due to technological limitations, this would constitute such reliance. For example, such reliance could occur in research or if the patient is being treated for co-occurring disorders for which close

consultation among specialists is paramount. Revocation of consent raises some of the same issues as withholding consent and conditioning treatment on consent for necessary disclosures. Thus, a program would need to explain to the patient when it is not feasible to stop or prevent a disclosure from occurring and discuss with a patient the consequences of revoking their consent in some circumstances. It is reasonable that a patient who seeks to revoke consent for disclosure to their health plan would be expected to make another arrangement to ensure payment which may include paying out of pocket for services.

Comment

Some commenters specifically addressed whether oral revocation of consent should be permitted and were nearly even in opposition and support. The several organizations favoring oral revocation expressed very strong support for recognizing this as a valid expression of patient choice. The rationales offered by commenters that did not support the proposed changes were the following:

- HIPAA requires written revocation.
- The CARES Act requires written revocation.
- Equating oral revocation with oral consent because part 2 programs are most likely to document oral consent in the part 2 record.
- Concern about how oral revocation would be documented and communicated to all entities that receive part 2 records.

Response

The statute, 42 U.S.C. 290dd–2(b)(C), states that revocation of a TPO consent must be in writing. At the same time, consideration should be given to other civil rights implicated in this interaction and the entity’s obligation under the relevant civil rights laws to provide assistance as needed to ensure meaningful access by enabling patients to effectuate a revocation.

Final Rule

The final rule adopts the proposed changes to the consent requirements in paragraph (a) with further modifications to paragraph (a)(4)(iii) to replace “HIPAA Privacy Rule” with “HIPAA regulations” and remove part 2 program from the statement about redisclosure according to the HIPAA regulations and to paragraph (a)(5)(iii) to require an opportunity to opt out of fundraising communications rather than requiring patient consent. The final rule adopts the proposed changes to the existing paragraph (b) of § 2.31 (Expired, deficient, or false consent) and

redesignates the content of paragraph (b) as a new paragraph (c). Additionally, the final rule adds a new paragraph (b) to require separate consent for the use and disclosure of SUD counseling notes, and a new paragraph (d) to require a separate consent for use and disclosure of records in civil, criminal, administrative, or legislative proceedings.

Section 2.32—Notice and Copy of Consent To Accompany Disclosure

Heading of Section

Proposed Rule

The Department proposed to change the heading of this section from “Prohibition on re-disclosure” to “Notice to accompany disclosure” because § 2.32 is wholly a notice requirement, while other provisions (§ 2.12(d)) prohibit recipients of part 2 records from redisclosing the records without obtaining a separate written patient consent. To ensure that recipients of part 2 records comply with the prohibition at § 2.12(d), § 2.32(a) requires that part 2 programs attach a notice whenever part 2 records are disclosed with patient consent, notifying the recipient of the prohibition on redisclosure and of the prohibition on use of the records in civil, criminal, administrative, and legislative proceedings against the patient.

Comments

We received no comments on the proposed change to the heading of this section.

Final Rule

The final rule is adopting the language of the proposed heading with a further modification to take into account the new paragraph (b) that we are adding, as discussed below. The new heading reads, “Notice and copy of consent to accompany disclosure.”

Expanded Notice of Prohibited Uses and Disclosures

Proposed Rule

The Department proposed to modify paragraph (a)(1) of § 2.32 to reflect the expanded prohibition on use and disclosure of part 2 records in certain proceedings against the patient, which includes testimony that relays information in a part 2 record and the use or disclosure of such records or testimony in civil, criminal, administrative, and legislative proceedings, absent consent or a court order.

In addition, the proposed language of the notice listed exceptions to the general rule prohibiting further use or

disclosure of the part 2 records by recipients of such records, which would allow covered entities, business associates, and part 2 programs who receive part 2 records for TPO based on a patient’s consent to redisclose the records as permitted by the HIPAA Privacy Rule. This exception also would apply to entities that received part 2 records from a covered entity or business associate under the HIPAA Privacy Rule disclosure permissions, although the legal proceedings prohibition would still apply to covered entities and business associates that receive these part 2 records. The Department stated that these changes are necessary to conform § 2.32 with 42 U.S.C. 290dd–2(b)(1)(B), as amended by section 3221(b) of the CARES Act, and proposed a statement in paragraph (a)(1) as follows:

This record which has been disclosed to you is protected by Federal confidentiality rules (42 CFR part 2). These rules prohibit you from using or disclosing this record, or testimony that describes the information contained in this record, in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient, unless authorized by the consent of the patient, except as provided at 42 CFR 2.12(c)(5) or as authorized by a court in accordance with 42 CFR 2.64 or 2.65. In addition, the Federal rules prohibit you from making any other use or disclosure of this record unless at least one of the following applies:

- Further use or disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or is otherwise permitted by 42 CFR part 2;
- You are a covered entity or business associate and have received the record for treatment, payment, or health care operations as defined in this part; or
- You have received the record from a covered entity or business associate as permitted by 45 CFR part 164, subparts A and E.

Comment

An individual commenter asserted that disclosures made by a part 2 program to a covered entity or a business associate for TPO and redisclosures made by a covered entity or business associate in accordance with the HIPAA regulations should not require a notice accompanying the disclosure as set out in § 2.32 of the proposed revisions.

The commenter stated that under the CARES Act, with the prior written consent of the patient, the contents of a part 2 program record may be used or disclosed by a covered entity, business associate, or program for TPO as permitted by the HIPAA regulations. Further, once disclosed to a covered

entity or business associate, the CARES Act provides that the information so disclosed may be redisclosed in accordance with the HIPAA regulations. The requirement of an accompanying written notice for each disclosure imposes a hurdle to the electronic exchange of information through a HIE and is not required under 42 U.S.C. 290dd–2. The commenter suggested that the provisions of 42 U.S.C. 290dd–2(c) operate independently and refer to uses and disclosures in proceedings rather than uses and disclosures by covered entities or business associates. Thus, the prohibition can be enforced independently by the patient in the course of any such proceeding. To the extent that an accompanying notice is determined to be necessary, it should be permissible to reference the provisions of 42 U.S.C. 290dd–2(c) in contractual agreements between the program, covered entities, and business associates rather than requiring that a notice accompany each disclosure.

An HIE described its reliance on contractual requirements in its agreements with data providers to ensure that it is notified of any limitations on its ability to share data prior to receiving that data. That practice will continue in response to the proposed changes contained in the NPRM. The commenter said that if the final rule includes a requirement for part 2 programs to notify data recipients, that requirement should be that they notify recipients when data is not received pursuant to a global consent for TPO, and that the operating assumption of parties receiving all forms of health data should be that it can be used consistently with the requirements of HIPAA and any relevant state laws or express contractual limitations.

Response

The notice does not establish a limitation on redisclosure but rather is intended to align the content of § 2.32 (Notice to accompany disclosure) with the requirements of 42 U.S.C. 290dd–2(b), as amended by the CARES Act.

As the Department noted in its 2010 HIE guidance and regulations, this notice was intended to inform downstream record recipients of part 2 and restrictions on redisclosure.²⁷⁷ The notice as we have finalized it in this rule, like the existing notice, continues to inform record recipients that the information they receive may not be

²⁷⁷ 83 FR 239, 241; See “Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE),” *supra* note 150.

used in legal proceedings absent patient consent or a court order. We believe that the notice remains applicable to redisclosures by part 2 programs, covered entities, and business associates to operationalize the continuing prohibition on use and disclosure of part 2 records in proceedings against the patient, which applies to redisclosures by recipients under § 2.12(d).

Also, consistent with 42 U.S.C. 290dd–2 and previous part 2 final rules, this final rule states in § 2.33 that “[w]hen disclosed for treatment, payment, and health care operations activities [. . .] to a covered entity or business associate, the recipient may further use or disclose those records as permitted by 45 CFR part 164, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.”

Simply citing 42 U.S.C. 290dd–2(c) in contractual agreements between the program, covered entities, and business associates rather than providing a notice to accompany each disclosure also is insufficient because this approach would fail to convey to the recipient of part 2 records essential information provided in the Notice to Accompany Disclosure under § 2.32 as finalized in this rule. However, business associate or other contractual agreements may refer to these provisions. Additionally, part 2 programs do not necessarily have contractual agreements with every recipient of records for uses and disclosures for TPO.

The text of 42 U.S.C. 290dd–2, as amended by the CARES Act, continues to emphasize limitations on use of part 2 records in civil, criminal, administrative, and legislative proceedings absent patient consent or a court order. Consistent with the statute and congressional intent reflected in the CARES Act, limitations on sharing information in proceedings within part 2 as finalized also remain distinct and more restrictive than analogous provisions within the HIPAA Privacy Rule.²⁷⁸

Comment

A commenter opined that the notice prohibiting redisclosure, which accompanies records disclosed with patient consent, should clearly identify whether the records are subject to the new redisclosure permissions or still protected by part 2.

Response

We believe this comment assumes a false dichotomy—that records are either subject to redisclosure or protected by part 2. Records that may be redisclosed according to the HIPAA standards—those for which a TPO consent was obtained—are still protected by the part 2 prohibition on use and disclosure in proceedings against the patient, absent consent or a court order under this part. However, assuming that the commenter is questioning how the recipient would identify records that are disclosed under a single consent for all TPO versus those that are disclosed under a more limited consent, we are finalizing an additional modification in § 2.32(b) to require that “[e]ach disclosure made with the patient’s written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided.” We believe this will provide the information recipients of records need to understand the redisclosure permissions that may be available.

Comment

A few medical professionals’ associations and other commenters said that retaining the Notice to Accompany Disclosure requirement means that the need to identify, segment, and segregate the data will persist to append the notice with each disclosure. One association requested that the Department exclude covered entities from this requirement.

Response

We do not believe that the notice requirement in § 2.32 is what may prompt segmentation of records or segregation of part 2 data. The continuing prohibition in § 2.12(d) on a recipient’s use or disclosure of records in legal proceedings must be effectively operationalized, and it is unclear how that can be accomplished unless the recipient is aware that the records are subject to the prohibition. We believe this can be accomplished within an electronic health exchange environment, and we are finalizing additional modifications to § 2.12(d)(2)(i)(C) to expressly state that “[a] part 2 program, covered entity, or business associate that receives records based on a single consent for all treatment, payment, and health care operations is not required to segregate or segment such records.” We believe health IT vendors are capable of updating or creating systems that manage consent, revocation, and other limitations on disclosure and redisclosure so long as the users of the

system have current knowledge of the type of data and the limitations on its use and disclosure. The final rule neither requires nor prohibits segregation of records or segmentation of data to accomplish these tasks. The short form of the notice has not changed and was created for use in an electronic health information exchange environment. We further recognize that the notice is required only for disclosures made with consent, and thus the notice would not be required for redisclosures as permitted by HIPAA for TPO or other permitted purposes when the initial disclosure was based on a TPO consent.

Comment

Some commenters supported proposed changes in whole or part and other commenters opposed or expressed mixed views of proposed changes.

A health care provider supported the proposed heading clarification, and further clarification of redisclosure rights for TPO by covered entities, business associates and part 2 programs as allowed by the HIPAA Privacy Rule. A health insurer supported aligning notices to accompany disclosures with the HIPAA Privacy Rule, particularly adding exceptions for the prohibition on use or disclosure of part 2 records for TPO. A few health information associations supported the Department’s proposal to include a Notice to Accompany Disclosure of records to instruct an organization of their ability to redisclose this information at the direction of the patient. A health system commenter said that it includes a disclosure statement on all records it releases. Therefore, it supported a Notice to Accompany Disclosure of part 2 records. However, the commenter recommended that the disclosure statement apply to all disclosures, including for TPO, stating that this would minimize time and operational burden of determining which records would require the disclosure statement.

Response

We appreciate the comments.

Comment

A health plan and at least a few associations recommended that the Notice to Accompany Disclosures be eliminated. A couple of commenters stated that retaining the notice to accompany the disclosure requirement will ensure that certain protections for part 2 records continue to “follow the record,” as compared to HIPAA, whereby protections are limited to PHI held by a covered entity or business associate. A few commenters stated that

²⁷⁸ See U.S. Dep’t of Health and Human Servs., “Court Orders and Subpoenas” (Nov. 2, 2020), <https://www.hhs.gov/hipaa/for-individuals/court-orders-subpoenas/index.html>.

this Notice means that the need to identify, segment, and segregate the data will persist to append the notice with each disclosure. And a few commenters requested that the Department eliminate this notice to align with HIPAA. At a minimum, the Department should excuse covered entity and business associate recipients of the part 2 records from the notice requirement, according to one commenter.

A few HIEs suggested that the § 2.32 notice requirement has been difficult to implement in electronic systems and across electronic networks in part because it requires the part 2 data to be treated and maintained differently than the rest of the clinical record. The commenters also suggested that it may also be legally impermissible under the CARES Act amendments, which mandate that once a patient's TPO consent is obtained, the disclosed part 2 record may be redisclosed in accordance with HIPAA and HIPAA does not require use of a prohibition on redisclosure notice.

Continuing to require the notice, according to these commenters, may effectively require the continued downstream identification, segmentation, and segregation of part 2 records, because segmentation/segregation will be necessary to properly apply, transmit, and display the notice in an electronic environment. Even though the Department emphasizes that the Notice to Accompany Disclosure is not a consent requirement (that is, it is not necessary for there to be a valid disclosure), these commenters believed that it was still a legal requirement that would carry stringent penalties under the HIPAA enforcement structure. Thus, requiring the notice would perpetuate the same barriers to SUD data sharing that the CARES Act amendment's changes were intended to eliminate.

Response

We appreciate input from these commenters, including concerns about continued segmentation of part 2 records that may result from providing the required notice. The introductory sentence of paragraph (a) of § 2.32 applies to each disclosure made with the patient's written consent, which includes the TPO consent finalized in this rule. We do not intend for this requirement to impede the integration of part 2 records with other PHI and have expressly removed any requirement to segregate or segment such records in this final rule at § 2.12(d)(2)(i)(C). Additionally, we believe the notice remains necessary to operationalize the continuing prohibition on redisclosures

for use in civil, criminal, administrative, and legislative proceedings against the patient, absent written consent or a court order under this part. We also believe that Congress attempted to balance permitting multiple redisclosures under a TPO consent for programs, covered entities, and business associates who are recipients of part 2 records and retaining the core patient protection against use of the records in proceedings against the patient. Congress could have amended part 2 to strike entirely the regulatory Notice to Accompany Disclosure or removed the consent requirement for disclosures to programs, covered entities, and business associates, but it did not do so; instead, Congress mandated a modified version of consent. Therefore, we interpret the existing requirement of a notice that accompanies each disclosure to apply to disclosures under a TPO consent in the same manner as for other disclosures with consent.

Comment

A commenter asserted that the proposed Notice to Accompany Disclosure language might confuse both patients and part 2 program recipients because it uses legalese and confusingly requires provision of the notice while simultaneously notifying covered entity and business associate recipients (and their downstream recipients) that they are not subject to part 2's use and disclosure restrictions. The commenter stated that proposed § 2.32 was silent regarding "intermediaries," which also seemingly conflicted with the part 2 consent form elements that restrict redisclosures by covered entities and business associate that function as "intermediaries" to only named member participants or participants that have a "treating provider relationship" with the patient. For these reasons, the commenter encouraged the Department to remove the notice requirement under this section or, at the least, not to require it for redisclosures made by covered entities and business associates (including those that operate as "intermediaries") and their downstream recipients pursuant to a patient's TPO consent.

Response

We appreciate input from these commenters and agree that the language of paragraph (a)(1) is more detailed and involved than paragraph (a)(2) but provide it as an option for programs that would find a complete explanation more useful and that are providing a paper copy of the notice. Providing the short form of the notice in paragraph (a)(2) is permitted. Thus, any program

that prefers to do so may continue to use the language of the abbreviated notice in paragraph (a)(2) rather than paragraph (a)(1). The shorter notice in paragraph (a)(2) states simply that "42 CFR part 2 prohibits unauthorized use or disclosure of these records," and should be readily understandable to recipients. The longer notice in paragraph (a)(1) further aligns with HIPAA. Both notices are consistent with a 2017 NPRM²⁷⁹ discussion and requirements that have been in place since 2018²⁸⁰ (for the abbreviated notice). The requirement added in paragraph (b) of this section that "[e]ach disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided" also should help clarify to recipients when records are subject to part 2 because it would indicate that SUD treatment records are being disclosed.

We disagree with the commenter's interpretation that paragraph (a)(1) notifies "covered entity and business associate recipients (and their downstream recipients) that they are not subject to part 2's use and disclosure restrictions" because the paragraph (a)(1) explicitly prohibits the recipient from using or disclosing the record in any civil, criminal, administrative, or legislative proceedings against the patient, absent consent or a court order.

With respect to the role of intermediaries, addressed in §§ 2.11 and 2.24, we have excluded programs, covered entities, and business associates from the definition of intermediary in this final rule. This relieves HIEs that are business associates from the requirements for intermediaries; however, all HIEs that receive part 2 records with consent (whether they are intermediaries or business associates) would need to provide the notice to accompany disclosure when redisclosing such records with consent.

Comment

Commenters urged OCR and SAMHSA to engage technology companies and intermediaries most likely involved in these types of disclosures and the accompanying notices to understand the feasibility and technical capacities in current technology. As the health system moves away from paper and the transmission of paper through processes like fax machines, having the technical capabilities in place for providers to move this information with the record is crucial, the commenter believed.

²⁷⁹ 82 FR 5485, 5487.

²⁸⁰ 83 FR 239, 240.

Engaging the organizations that govern this work will give OCR and SAMHSA a clearer picture of understanding related to the ability for an accompanying notice of disclosure to be included with a part 2 record and consent form.

Response

We acknowledge the commenter's concerns about EHRs and the need to ensure they have the capabilities necessary to transmit information about prohibited uses and disclosures and the scope of consent on which a disclosure is based. OCR, SAMHSA, and other Federal partners are collaborating to support EHRs and health IT within the behavioral health sector.²⁸¹ We also may provide additional guidance on this section after the rule is finalized.

Comment

A commenter said that one concern they had with including a Notice to Accompany Disclosure on every patient record that is being redisclosed is the ability of EHR systems to ingest that information. The commenter explained that a v2x HL7 ADT message (or for that matter a lab message) does not include this type of language.²⁸²

The commenter suggested that even if an HL7 message could be created with the information, it is unclear that receiving systems are currently able to populate the field in the ADT message or will be able to consume the message. The commenter is not aware of any designated spot for that type of language on any interstate event notification specification. Therefore, if a hospital wanted to share an admission or discharge notice for a patient admitted to a substance use unit, they couldn't easily include the language in the notification. Even if the sending part 2 program could transmit the message, the downstream receiver may not be able to receive it.

The commenter suggested that it would be possible to put a confidentiality/protection flag on an ADT message—but not general language like the notice to accompany disclosure language.

Response

We have previously noted that EHR systems are beyond the scope of this rulemaking. However, the abbreviated notice in § 2.32(a)(2) is intended to support use of EHRs, and the abbreviated notice remains a valid

option. OCR, SAMHSA, and OCR continue to work to support EHR implementation and may provide guidance on these issues after this rule is finalized.

Comment

An academic medical center said that it saw no value in adding the language regarding redisclosure to part 2 records and believed that recipients of these notices were not familiar with part 2 restrictions. The commenter stated that it is able to affix stamps on records that are being disclosed but from a practical perspective does not believe the stamp is value added. Recipients may not know what a part 2 program is. The commenter has other patients throughout the medical center that are not being discharged from part 2 program that also have been or are being treated for SUD conditions and receive medications specific to SUDs.

Response

We appreciate the commenter's perspective on patients' and recipients' lack of understanding about part 2 protections. We hope that the revised Patient Notice will improve part 2 patients' understanding of their confidentiality rights under part 2 which should also enhance their appreciation for the prohibition on redisclosure in proceedings against patients. As explained in this rule, we continue to believe that the Notice to Accompany Disclosures under § 2.32 provides important protections to part 2 patients, and the lack of these protections for other patients is not a justification for reducing or removing protections for part 2 patients. As stated in the 2017 final rule, part 2 does not apply to health information unrelated to SUDs, such as patient treatment for unrelated medical conditions.²⁸³

Comment

A SUD provider and a health plan requested clarification about the applicability of the notice requirement to recipients who redisclose records, including whether the requirement for the Notice to Accompany Disclosure applies only to part 2 programs, or whether it also applies to covered entities, business associates, and intermediaries that might receive and redisclose the patient's PHI. The commenters asked, collectively, whether an HIE, covered entity, and business associate must attach the notice on part 2 records being redisclosed in accordance with the HIPAA privacy regulations, such as in

paragraph (a)(2): "42 CFR part 2 prohibits unauthorized use or disclosure of these records."

Response

The existing introductory language of paragraph (a) applies the notice requirement to "[e]ach disclosure made with the patient's written consent."²⁸⁴ The abbreviated notice under paragraph (a)(2) was primarily intended to support EHR systems. As the Department explained in 2018, "SAMHSA has adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems."²⁸⁵ Though the notice under paragraph (a)(2) has been modified in this final rule to include the word "use," it remains largely as adopted in 2018. At that time the Department also said that it "encourages part 2 programs and other lawful holders using the abbreviated notice to discuss the requirements with those to whom they disclose patient identifying information."²⁸⁶ An HIE may elect to use the abbreviated notice under paragraph (a)(2) or can choose to use one of the notices permitted under paragraph (a)(1). Covered entities and business associates are referenced in § 2.32(a)(1).

Comment

An HIE urged the Department to include language that will resonate with the patient as opposed to those in the health care space. The commenter stated that in the NPRM, the Department proposed to require the consent form to notify the patient about how covered entities and business associate recipients may use and redisclose information as permitted by HIPAA. The commenter expressed concern that this was problematic for two reasons. First, this is not an existing requirement under HIPAA and the objective of the rule is to align part 2 with HIPAA. Second, the terms covered entity and business associate are not terms some patients may be aware of. To include this requirement, according to the commenter, could introduce legalese in the patient-facing workflow and be contrary to calls to improve the rule's utility for patients. The commenter asked the Department to use standard language required under HIPAA that notifies individuals that not all recipients are subject to the same laws.

²⁸¹ See "Behavioral Health," *supra* note 133.

²⁸² Note Health Level 7 is discussed in ONC guidance at <https://www.healthit.gov/topic/standards-technology/standards/fhir-fact-sheets>. ADT is a reference to admit, discharge, transfer.

²⁸³ 82 FR 6052, 6089.

²⁸⁴ 52 FR 21796, 21810.

²⁸⁵ 83 FR 239, 240.

²⁸⁶ 83 FR 239, 240.

Response

We appreciate input from these commenters and acknowledge the concerns they express. But we disagree that the Notice to Accompany Disclosure will confuse patients. First, we anticipate that most recipients of these notices will be health professionals or staff such as those working for part 2 programs, covered entities, and business associates rather than patients themselves. Second, the provisions of this rule, including §§ 2.22, 2.31, and 2.32 are consistent with the provisions of the HIPAA Privacy Rule as explained above. However, even with this rule and additional alignment with HIPAA fostered by the CARES Act some part 2 provisions remain distinct from requirements in HIPAA. Likewise, while part 2 consent forms under § 2.31 must include specified required elements for written consent there is no requirement these forms use such terms as “covered entity” or “business associate.” As noted above, we may provide additional guidance or template notices or model forms to help clarify requirements of this final rule. Finally, the abbreviated notice in § 2.32(a)(2) is especially brief and easy to understand, although we believe the lengthier notice in paragraph (a)(1) is fairly easy to understand as well.

Comment

A health plan recommended that the Department clarify that these redisclosures do not need to be included in an accounting of disclosures under § 2.25. Requiring a notice to accompany redisclosures would run counter to the general exemption of TPO disclosures under HIPAA’s accounting provisions.

Response

With respect to the right to an accounting of redisclosures, the applicability of § 2.25 would depend on the status of the recipient. For example, a covered entity or business associate would be subject to 45 CFR 164.528 for redisclosures. A part 2 program that rediscloses records received from another part 2 program would be subject to § 2.25 for such redisclosures that fall within the scope of § 2.25 in the same manner as for disclosures. The accounting of disclosures requirements under § 2.25 do not distinguish between disclosures and redisclosures, but focus on whether a disclosure is made with consent and the purpose of the disclosure or redisclosure. The § 2.25 requirements are distinct from the required notices to accompany disclosures under § 2.32. Therefore, the

accounting of disclosures under § 2.25 would not need to include a separate and distinct list of redisclosures accompanied by a notice under § 2.32.

Comment

A commenter recommended that HHS move proposed item (iv) of the statement in § 2.32(a)(1) to the main text of the statement, so that it does not appear to be one of the exceptions following items (i), (ii), and (iii) of the statement. The commenter also suggested revised language for these provisions.

Response

We retain in the statement in § 2.32(a)(1) the following notification: “[a] general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31).” We have moved this information to the main text which is consistent with the commenter’s suggestion.

Comment

An advocacy group opined that proposed changes to this section will cause confusion. The commenter said that at this time all recipients of records are subject to the same redisclosure prohibition: they may only use or disclose the records with patient consent, pursuant to a court order, or subject to one of the other limited exceptions in part 2 that apply to lawful holders. However, according to this commenter, this rulemaking introduces a new standard for some recipients who receive records pursuant to a TPO consent: these recipients may redisclose records pursuant to the HIPAA Privacy Rule, except if the records will be used against the patient in a legal proceeding. A recipient of part 2 records, however, will have no way of knowing which redisclosure standard applies to the records they receive: the standard part 2 redisclosure prohibition, described in proposed item (i) in the statement in § 2.32(a)(1), or redisclosures as permitted by the HIPAA Privacy Rule except for legal proceedings against the patient, described in proposed item (ii) in the statement in § 2.32(a)(1).

Response

We appreciate the comment and agree that with the additional changes to consent in §§ 2.31 and 2.33, the Notice to Accompany Disclosure is insufficient to provide needed information to the recipient about the scope of consent that pertains to the disclosed records. To address this issue, we are also finalizing a new provision in paragraph (b) of this

section to require each disclosure made with the patient’s written consent to be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided, as discussed below.

Comment

A medical professionals association said that we should require part 2 programs to give health care providers adequate written notice well in advance of sharing any part 2 record, clearly explaining that such records are subject to additional Federal confidentiality regulations and include clear guidance for non-part 2 providers to understand their obligations and options concerning such records once received.

Response

We believe that § 2.32(a) as finalized clearly notifies the recipient of redisclosed records whether the records are subject to part 2. The new requirement in paragraph (b) of this section, discussed below, will provide additional information to recipients about the scope of the consent that applies.

Final Rule

The final rule adopts the proposed language of § 2.32(a) without further substantive modification, and finalizes proposed item (i) of the statement in § 2.32(a)(1) as part of the statement in § 2.32(a)(1).

Copy of Consent To Accompany Disclosure

Request for Comment

Although we did not propose requirements for consent management, we requested comment throughout the NPRM on how proposed changes to consent, revocation, and requests for restrictions could be implemented, the experience of entities that have already operationalized aspects of the proposed changes, potential unforeseen negative consequences from new or changed requirements, and data relating to any of these.

Overview of Comments

We received many comments addressing cross-cutting issues involving data segmentation and segregation of records, use of HIEs for exchange of ePHI and part 2 records, how to track consent and consent revocation, and how to operationalize patients’ requests for restrictions on disclosures for TPO. We have responded to these comments throughout the preamble to the final rule in relation to applicable regulatory provisions, and here we respond to comments that pertain to tracking consent (which is

required in §§ 2.31 and 2.33), both global (*i.e.*, TPO consent) and granular (for a specific use and disclosure). Of the commenters that addressed whether the rule should require a copy of consent to be attached with each disclosure of records, a majority opposed such a requirement, several supported it, and a few responded with other viewpoints. A mix of professional associations, SUD providers, and advocacy organizations provided views on both sides of the question; however, all health plans, health IT vendors, and HIE/HIN organizations that weighed in opposed the idea and all government entities that voiced an opinion supported providing a copy of the consent.

Comment

A medical professionals association urged the Department to ensure that, going forward, patient information will be tagged and limited to the purpose of TPO. The agencies can incentivize compliance with these goals through enforcement actions and penalties for noncompliance. The commenter believes that technology can assist physicians with increasing the flow of information while maintaining privacy and a patient's consent. To do so, information should be tagged to identify where the information originated, for what purposes it can be disclosed, and to whom. Another medical professionals' association asked the Department to facilitate collaboration with ONC and health IT vendors to develop technical standards and feasible certification criteria to identify, tag, segregate, and remove specific data based on type of care, provider, and patient consent. The commenter also stated that HHS should provide incentives and support to clinicians, practices, and EHR vendors—particularly those designed for specialty settings or small practices—in designing and adopting health IT that meets these objectives. A provider health system believed that even if HIPAA and part 2 records are treated as PHI for most of the situations, there will still be the need to identify part 2 records due to any directed restrictions and the legal proceedings prohibition. This could become further complicated as part 2 records and PHI are intermingled. While the provider health system supported alignment of HIPAA and part 2, it requested the Department provide guidance about how records will be denoted and differentiated to ensure compliance.

Response

We appreciate input from these commenters, including suggestions to tag or segregate part 2 records. We acknowledge concerns about data segmentation and address it further in the discussion of § 2.12. The continuing prohibition in § 2.12(d) on a recipient's use or disclosure of records in legal proceedings must be effectively operationalized, and it is unclear how that can be accomplished unless the recipient is aware that the records are subject to the prohibition. Although the Department may provide further guidance in relation to data segmentation, tagging, or tracking, we are not requiring specific technology or software solutions.

Comment

A trade association suggested that HHS is maintaining separate underlying regulatory structures for SUD patient records and all other patient data, meaning EHR vendors will need to distinguish between the two types of records. Some SUD patients may not provide consent or revoke their consent throughout the course of their treatment, meaning their record will need to be flagged differently. This is a significant health IT challenge that is not addressed in the NPRM. The commenter stated that HHS should ensure that there is ample time and resources for health IT vendors to update their capabilities and adapt to the evolving operational needs of health care providers.

An academic medical center suggested that information about the scope of consent be included in the notice that is required to accompany disclosures of part 2 records and that this would be the simplest way to communicate the patient's intent and have that intent stay with the actual records downstream.

A health IT vendor recommended that the Department explore further how revocation becomes known, and if it means that the HIE must directly record the status of a revocation (and how this is done) or if the HIE relies on some kind of "polling" of the part 2 program to ascertain if a valid consent remains effective by interrogating the part 2 program electronically for whether a valid consent exists or if an applicable consent has been revoked. In the end, a revocation needs to not only limit future disclosures but also limit disclosures of any part 2 records an HIE already may possess should they store patient records.

Among others, a health IT vendor, a health care provider, and a health insurer believed that part 2 programs

should not be required to provide a copy of the written patient consent when disclosing records. They believe the notice to accompany disclosures already required under the § 2.32 is sufficient to alert the recipient of potential restrictions regarding redisclosure and the requirement would not align with disclosures for TPO under HIPAA. A health insurer suggested that allowing a part 2 program to retain the consent for future auditing and use or disclosure needs is sufficient and also helps to share only the minimum necessary PHI. If the Department were to also require provision of the written consent authorizing the disclosure, it would place an unnecessary administrative burden on both the part 2 program and the recipient of records. Even more problematic, such a requirement would create a corresponding duty for the recipient of records to evaluate the legal sufficiency of the consent related to the part 2 program's disclosure. The recipient of records should not be placed in the position of identifying and correcting errors in a part 2 program's disclosure, or assuming any potential downstream liabilities that may result.

An insurance association supported the use of electronic processes whenever feasible. In addition, to reduce the burden on part 2 programs and to ensure that HIPAA entities can act promptly on part 2 data, the association asked that the Department clarify in final regulations that HIPAA entities that receive part 2 data may accept that the data was disclosed pursuant to a TPO consent unless otherwise notified in writing. This is particularly important in industries such as pharmacy benefits management, where data is transmitted in huge volumes in real time, and there is no consistent mechanism currently available to "flag" certain records as containing part 2 data, nor explain the legal basis on which the data were disclosed.

Response

We acknowledge commenter concerns about how to manage consent and any limitations on consent within EHRs and through HIEs and the disadvantages of segmenting data and segregating records. Although we are finalizing a modification to § 2.12 to expressly state that "[a] program, covered entity, or business associate that receives records based on a single consent for all treatment, payment, and health care operations is not required to segregate or segment such records[.]" some means to ensure that records are used and disclosed according to the scope of the

consent will be needed. Thus, we look to the consent provided by the patient and the existing requirement to attach a Notice to Accompany Disclosure as solutions and are adding a new requirement in § 2.32(b) to require that a copy of the consent be attached to each disclosure for which consent is required. The attached consent may be combined with the required Notice to Accompany Disclosure in § 2.32(a). This will significantly reduce any administrative burdens associated with the new requirement.

We are finalizing a new requirement in this section to require that each disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided. We believe that by putting in regulatory text that the consent must accompany the disclosure or provide a clear description of the scope of the consent, the recipient will be able to accurately use and disclose the part 2 records as the patient intended. Additionally, where feasible, part 2 programs should convey to recipients when a consent has been revoked to ensure that only consented information is exchanged. Combining a copy of the consent with the required Notice to Accompany Disclosures in § 2.32 is one way this requirement may be implemented, though it is not the only potential approach to tracking consent, redisclosure and revocation of consent. Both paragraphs (a) and (b) of this section address concerns about ensuring recipients of records understand whether or not the records are subject to part 2.

We acknowledge that there are technical challenges associated with complying concurrently with HIPAA and part 2 and that time and resources are needed to update technical and procedural capabilities. The recommendation for recipients to assume TPO consent has been provided unless otherwise notified in writing does not address how recipients other than programs, covered entities, and business associates would learn about this assumption. Nor does this recommendation address how a program (*i.e.*, a discloser) would know in advance whether a recipient is a program, covered entity, or business associate to whom the TPO consent assumption applies. We evaluated this recommendation, but are concerned that the negative requirement (*e.g.*, not to provide consent unless it is other than for TPO) places undue burden on the disclosing program to decide when and when not to attach a copy of the consent.

We believe the concern that receipt of notice may transfer liability for improper disclosures from the part 2 program to the recipient is misplaced. However, the recipient incurs an obligation for complying with part 2 requirements that apply to them, namely, the prohibition on use or disclosure of the records for use in proceedings against the patient, absent consent or a court order under this part.

Comment

Regarding intermediaries and tracking consent, an HIE association suggested that part 2 providers may need to include in the consent form a place for patients to indicate whether they provide consent for disclosure to the intermediary. For additional information on how an intermediary would accept or track patient consent for data redisclosure, the commenter recommended OCR and SAMHSA consult nationwide HINs, as well as ONC, to understand how current state HINs and the TEFCA could impact this landscape.

Response

We appreciate the comment and the reference to TEFCA. As discussed above in relation to § 2.31 (Consent requirements), a consent to disclose records via an intermediary must contain a general designation as well as additional information about the recipient(s). Thus, we believe the final rule provides for the consent form to have space for an intermediary to be named as the commenter suggests. We note, however, that we are excluding business associates from the final rule definition of "intermediary," thus HIE business associates will not be subject to the intermediary consent requirements. Instead, HIEs that are business associates will fall within the requirements for a general designation for the TPO consent which does not require specifically consenting to use of an HIE. We received many informative public comments from HIEs/HINs with respect to consent (and revocation) management and will continue to consult with our partner agencies within the Department. OCR, SAMHSA, and others are collaborating to support participation by behavioral health entities in health IT and EHRs, including TEFCA.

Final Rule

This final rule adopts further modifications in § 2.32 by adding a new paragraph (b) providing that each disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear

explanation of the scope of the consent provided.

Section 2.33—Uses and Disclosures Permitted With Written Consent

Proposed Rule

Section 2.33 currently permits part 2 programs to disclose records in accordance with written patient consent in paragraph (a) and permits lawful holders, upon receipt of the records based on consent for payment or health care operations purposes, to redisclose such records to contractors and subcontractors for certain activities, such as those provided as examples in paragraph (b). The Department proposed substantial changes to paragraph (b) to apply the new consent structure in § 2.31 for a single consent for all TPO by: applying HIPAA standards for uses and initial disclosures for TPO, creating two new categories of redisclosure permissions, and revising the existing redisclosure permission. This would align § 2.33 with the statutory authority in 42 U.S.C. 290dd–2(b)(1), as amended by section 3221(b) of the CARES Act. The first change would permit part 2 programs, covered entities, and business associates that have obtained a TPO consent to use and disclose a part 2 record for TPO as allowed by HIPAA. With respect to redisclosures, proposed (b)(1) would permit part 2 programs, covered entities, and business associates that have received a part 2 record with consent for TPO to redisclose the records as permitted by the HIPAA Privacy Rule, except for proceedings against a patient which require written consent or a court order. The second category, in proposed paragraph (b)(2), would permit part 2 programs that are not covered entities or business associates that have received a part 2 record with consent for TPO to further use or disclose the records as permitted by the consent. The third category, in proposed paragraph (b)(3), would apply to lawful holders that are not business associates, covered entities, or part 2 programs and have received part 2 records with written consent for payment and health care operations purposes. This provision would permit the recipient to redisclose the records for uses and disclosures to its contractors, subcontractors, and legal representatives to carry out the intended purpose, also subject to the limitations of proposed subpart E of part 2 pertaining to legal proceedings. A lawful holder under this provision would not be permitted to redisclose part 2 records it receives for treatment purposes before obtaining an additional written consent from the patient.

Paragraph (c) proposed to require lawful holders that are not covered entities or business associates and that receive records based on written consent to have contracts in place if they wish to redisclose the records to contractors and subcontractors. The Department proposed to exclude covered entities and business associates from the requirements of paragraph (c) because they are already subject to the HIPAA Privacy Rule requirements for business associate agreements.

Overview of Comments

Most commenters on the single consent for all future TPO supported the proposal, and all but one of the supportive commenters represented organizations. Supportive organizations included several professional associations, health systems, and state or local governments. A few SUD providers also supported the proposal. The views expressed by these commenters in support of the proposal included the following:

(a) reducing stigma of persons with SUD by integrating SUD treatment and SUD treatment records, respectively, with general health care and PHI;

(b) reducing burdens on the health care system by aligning part 2 requirements more closely with the HIPAA regulations; and

(c) improving care coordination, continuity of care, and patient safety as a result of greater access to complete information to treat patients comprehensively and obtain services to support their recovery.

As an example, a commenter asserted that the proposal may make it easier for the state Medicaid agency to gain input about barriers for patients receiving SUD services such as co-occurring medical or behavioral conditions, or to address social determinants of health that impede treatment or recovery. An association of state hospitals and health systems illustrated what it views as the need for an aligned consent process, citing what it regards as differing regulatory requirements that may “cause confusion, and even fear, among treating providers, at times leading them to withhold information that may be shared.”

Response

We appreciate the comments about the proposed changes to implement the statutory requirements for uses and disclosures with a single consent for all future TPO and permitted redisclosures by certain recipients. The rationales offered in support—reducing stigma, integrating and coordinating behavioral health care, and reducing health care

entities’ burdens—are key aims of this final rule.

Comment

Commenters favoring the proposal also appreciated the reduction in the number of consents needed for uses and disclosures of part 2 records as well as the reduction in consents required for redisclosures of records. A health plan remarked that “requiring multiple consents . . . adds confusion and distrust to an already underserved population,” and further stated that “[a] single consent will give stakeholders a single reference point to review the patient’s permissions and any relevant requested restrictions.”

Response

We agree that the changes to allow a single consent for all future TPO will reduce the number of consents that part 2 programs will need to obtain from patients as well as the number of consents that recipients will need to obtain for redisclosures of part 2 records. We have estimated the amount of that reduction and describe it more fully in the costs-benefits analysis in the RIA for this final rule.

Comment

A health system pointed out that people suffering from untreated SUD are among the highest utilizers of health care services and asserted the importance of reducing barriers to integrated care. The commenter stated its belief that the existing part 2 regulation was written before the current models of care and related best practices were established and that it now is a barrier to coordinated care for patients with SUD.

Response

We appreciate this feedback and recognize the importance of integrated health records for providing integrated and coordinated health care, including for treatment of SUD in a whole person context. This perspective underpins one of the key purposes of section 3221 of the CARES Act that is being implemented in this final rule.

Comment

Several commenters who supported the TPO consent and redisclosure proposal thought that it did not go far enough to align with the HIPAA Privacy Rule and urged the Department to allow for Patient Notice to replace consent for TPO disclosures of part 2 records.

Response

The CARES Act amendments to 42 U.S.C. 290dd–2 did not remove the

written consent requirement for disclosure of part 2 records. Thus, the Department lacks authority to replace a patient’s written consent with Patient Notice. We anticipate that patient consent will remain as a foundation for protection of part 2 records.

Comment

The commenters that opposed the proposals for a single TPO consent and redisclosure as allowed by HIPAA presented a largely unified set of views developed by a core group of organizations representing addiction treatment professionals, advocacy and policy organizations, and SUD providers. These commenters strongly believed that the current requirement of consent for each disclosure and segregation of part 2 records offers patients the needed confidence to enter and remain in treatment and develop the necessary therapeutic trust to share details of their lives and struggles with SUD. The commenters acknowledged that discrimination is often perpetuated by those outside of the health care system as a result of the criminalization of the use of certain substances and they oppose finalizing the loosened consent provisions until the Department issues the statutorily required antidiscrimination protections. These commenters strongly supported regulatory requirements to ensure patients’ trust in the SUD treatment and the health care system. Several other commenters agreed with this set of core comments.

Response

We appreciate these comments and the concerns expressed for access to SUD treatment, patient trust in the relationship with treatment providers, patients’ privacy expectations, the societal harms of discrimination against patients with SUD, and the Department’s obligations to fully implement section 3221 of the CARES Act. We believe that the changes finalized to § 2.33 herein are necessary and reasonable as a means to implement to 42 U.S.C. 290dd–2(b), as amended by the CARES Act.

Comment

Several commenters addressed whether recipients of records based on a TPO consent (part 2 programs, covered entities, and business associates) should be able redisclose the part 2 information for any purposes permitted by HIPAA or only for TPO purposes. And some of these asserted or recommended that the rule should permit redisclosures as permitted by the HIPAA Privacy Rule (not limited to TPO). A few medical

professional associations recommended that redisclosures by recipients under a TPO consent should only be permitted for TPO purposes. This would maintain patient privacy and be consistent with the consent provided. One association suggested this could be accomplished by tagging data associated with the TPO consent. Another suggested that limiting redisclosure to TPO would permit PHI to be integrated into part 2 records systems, thus partially furthering the goal of integrating health information.

Response

The changes to consent finalized in this rule are based on 42 U.S.C. 290dd–2, as amended by the CARES Act. With respect to redisclosures by recipients under a TPO consent, paragraph (b)(1)(B) of the statute states that once records are used and disclosed for TPO they may be further disclosed in accordance with the HIPAA regulations. The clear terms of the statute apply the initial use and disclosure permission to a part 2 program, covered entity, or business associate for TPO as permitted by the HIPAA regulations, and then allow disclosed records to be more broadly redisclosed provided that it is according to the HIPAA regulations. We interpret the broader HIPAA redisclosure permission to apply only to the recipient. Thus, a part 2 program that obtains a TPO consent is limited to using or disclosing the record for TPO purposes—it cannot obtain a TPO consent and “disclose” the records to itself to trigger the permission to redisclose according to the HIPAA regulations and avoid overall compliance with part 2. We believe that a disclosure implies a recipient other than the entity making the disclosure and the only recipients authorized by the statute to redisclose records according to the HIPAA regulations are those that are otherwise subject to HIPAA, which are covered entities (including those that are also part 2 programs), and business associates. The redisclosure permission refers to “in accordance with HIPAA,” and we believe that part 2 programs that are not subject to HIPAA would not be qualified to make such redisclosures in that manner. Such part 2 programs are not subject to the same obligations as covered entities, such as adopting written policies and procedures for handling PHI, training members of the workforce on their policies and procedures, and adhering to the HIPAA Security Rule requirements for safeguarding electronic PHI.

The prohibition on using and disclosing records in civil, criminal, administrative, and legislative

proceedings against a patient remains effective once records are disclosed and this raises the issue for recipients of potentially tracking, tagging, or otherwise identifying the part 2 data that must be protected from such uses and disclosures absent written consent or a court order under subpart E of part 2.

The last sentence of paragraph (b)(1)(B) of the statute provides that the patient’s right to request restrictions on uses and disclosures for TPO applies to all disclosures under paragraph (b)(1), which includes redisclosures by recipients of records. Thus, a recipient entity that complies with a patient’s request for restrictions on disclosures for TPO is acting in accordance with the HIPAA regulations. We believe that Congress intended to emphasize the availability of patient-requested restrictions by the placement of this right in the part 2 statute with the redisclosure permission and including it in both the Rules of Construction and the Sense of Congress in section 3221 of the CARES Act.

Final Rule

The final rule adopts the proposed changes to the header and to paragraph (c) of § 2.33 without modification. For clarity, the final rule further modifies paragraph (a) by adding “use and” before “disclosure” and by redesignating the content of the paragraph as paragraph (a)(1) and adding a new paragraph (a)(2) that provides, “[w]hen the consent provided is a single consent for all future uses and disclosures for treatment, payment, and health care operations, a part 2 program, covered entity, or business associate may use and disclose those records for treatment, payment, and health care operations as permitted by the HIPAA regulations, until such time as the patient revokes such consent in writing.” This new provision clarifies the regulatory permission for use and disclosure for TPO that previously was only implied by a general reference to the consent requirements in § 2.31, and it more explicitly states what the statute provides relating to reliance on the HIPAA standards. As a result of this change, part 2 programs will be able to rely on the HIPAA regulations when using or disclosing part 2 records for TPO in many instances, and covered entities and business associates will not need to silo part 2 records once a TPO consent has been obtained.

This rule also finalizes proposed paragraph (b)(1) with modifications to more closely align with the statutory language by changing “further use and disclose” to “further disclose” and

replacing “as permitted by 45 CFR part 164” with “in accordance with the HIPAA regulations.” For clarity, the final rule also removes “a program” from paragraph (b)(1) because part 2 programs that are not covered entities or business associates are separately addressed in paragraph (b)(2). The rule finalizes proposed paragraph (b)(2) with the further modification of changing “further use and disclose” to “further disclose” as in paragraph (b)(1). The rule finalizes proposed paragraph (b)(3) with the further modification of removing the exclusion of “part 2 program.” This has the effect of applying the existing requirements of paragraph (b)(3) to a part 2 program when it is a lawful holder (*i.e.*, a recipient of part 2 records) and ensures that redisclosure in accordance with HIPAA is limited to covered entities and business associates. We clarify here that paragraph (b)(3) applies in situations where the written consent is only for payment and/or health care operations and does not include treatment.

Section 2.34—Uses and Disclosures To Prevent Multiple Enrollments

Comment

While not proposed in the NPRM, an individual stated that central registries have not been classified as a QSO or a business associate and therefore, there are no safeguards protecting the information exchanged between central registries and non-member treating providers under § 2.34(d). The commenter further stated that the patient consents to the use or disclosure of their SUD information to the central registry but not to a non-member treating prescriber.

Response

We appreciate the suggestion to classify central registries as a QSO or a business associate; however, that suggestion is outside the scope of the current rulemaking.

Final Rule

The final rule adopts the proposed addition of the language in § 2.34(b) of “use of information in records” instead of just “use of information” in this section to make clear that this provision relates to part 2 records. The final rule also adopts the proposed replacement of the phrase “re-disclose or use” to “use or redisclose” as it relates to preventing a registry from using or redisclosing part 2 records, to align the language of this provision with the HIPAA Privacy Rule. A provider health system supported the alignment of “use or redisclose” and there were no other comments on these proposals.

Section 2.35—Disclosures to Elements of the Criminal Justice System Which Have Referred Patients

Proposed Rule

Section 2.35 outlines conditions for disclosures back to persons within the criminal justice system who have referred patients to a part 2 program for SUD diagnosis or treatment as a condition of the patients' confinement or parole. The Department proposed to clarify that the permitted disclosures would be of information from the part 2 record and to replace the term "individual" within the criminal justice system with "persons" consistent with similar changes throughout this rule. The Department also proposed to add the phrase "from a record" after the term "information" to make clear that this section regulates "records." In addition to requesting comment on the proposed wording changes, the Department invited comments on whether the alternative term "personnel" would more accurately cover the circumstances under which referrals under § 2.35 are made.

Comment

One individual commenter asserted that the alternative term "personnel" was too broad in this context and would create circumstances that could compromise patient confidentiality. This individual also commented that replacing the term "individual" with the term "person" would be more acceptable. Another commenter, a provider health system, expressed support for the term change from "individual" to "person" and stated that the term "person" is preferable to "personnel" since the term "personnel" may inadvertently imply employment status while the term "persons" would accurately reflect referrals from the criminal justice system regardless of status as an employee, independent contractor or other individual on behalf of the criminal justice system.

Response

We agree with these commenters for the reasons discussed in the NPRM.

Comment

Several advocacy organizations and a health IT vendor commented that the Department's proposed changes unnecessarily limit diversion to court based programs. These commenters recommended certain changes to the proposal that, in their opinion, would include pre-arrest diversion as well as other types of law enforcement deflection to avoid the court system and direct the patient into treatment and

services. In § 2.35(a), these commenters recommended changing "A part 2 program may disclose information from a record about a patient to those persons within the criminal justice system who have made participation in the part 2 program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if . . ." to "A part 2 program may disclose information from a record about a patient to those persons within the criminal justice system who have made participation in the part 2 program a condition of *the filing, prosecution, or disposition* of any criminal proceedings against the patient or of the patient's parole or other release from custody if . . ." (emphasis added).

For § 2.35(a)(1), these commenters recommended changing "(e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole officers responsible for supervision of the patient)" to "(e.g., a police officer or a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole officers responsible for supervision of the patient)" (emphasis added).

Response

We appreciate the detailed recommendations for regulatory text in these comments. We also acknowledge the important social policy raised, to promote treatment over referral to courts. However, we believe the consent process is sufficient for the operation of diversion and deflection initiatives, without a need for the Department to loosen confidentiality restrictions, because it allows patients to consent to the release of part 2 records for such initiatives if they wish to do so.

Final Rule

The Department adopts the proposed changes without modification.

Subpart D—Uses and Disclosures Without Patient Consent²⁸⁷

Section 2.51—Medical Emergencies

Proposed Rule

In § 2.51(c)(2) the Department proposed for clarity replacing the term "individual" with "person" such that this now requires a part 2 program to document the name of the person making the disclosure in response to a medical emergency.

²⁸⁷ As described below, the Department adopts the proposal to add "Uses and" to this heading to more accurately reflect the scope of activities regulated in this subpart.

Comment

An advocacy group recommended that the proposed change to § 2.51 (Medical emergencies), be withdrawn. The commenter suggested that as part of its efforts throughout the rulemaking to standardize regulatory language, HHS proposed to replace the word "individual" with the word "person" in the documentation requirements. HHS proposed to define "person" by reference to the HIPAA Privacy Rule as a "natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private." The commenter said that in its view even though the Department states this change will promote clarity it will actually result in less clarity for patients, who may no longer be able to tell who disclosed their part 2-protected information to 911 and medical personnel. The patient already knows that the part 2 program was the "person" making a disclosure of part 2 records during a medical emergency. For this reason, it is the identity of the individual making the disclosure that is important to document. In general, the organization supported the efforts throughout the rulemaking to streamline language by replacing the phrase "individual or entity" with the word "person," but in this instance the change will diminish patients' rights and transparency with no clear benefit to impacted patients.

Response

We discuss our changes to definitions, including the term "person" in § 2.11. Commenters generally supported this proposed change as providing clarity and helping to align with HIPAA. However, we acknowledge that in this instance replacing the term "individual" with the term "person" could result in less transparency about who disclosed the patient's record during an emergency; however, under the wording change a part 2 program is not prevented from identifying the individual who disclosed the part 2 information. Further, there may be instances or treatment settings where documenting only the name of the disclosing entity, rather than the individual, is needed to protect the safety of program staff.

Comment

A few health information associations supported the ability for providers, under certain circumstances such as medical emergencies, to access, use, and disclose patient part 2 data when necessary. It is important for providers

to have access to all points of decision-making in a medical emergency to ensure patients are protected physically both in the short and the long term. A health care provider and medical professionals' association also supported the proposed changes in this section.

Response

We appreciate the comments on our changes in this section of the rule.

Comment

Another commenter asserted that a workflow obstacle occurs when patients previously treated in their part 2 program present to the emergency department for care. The emergency department personnel are blinded from accessing care notes which can be relevant to the emergency event. In addition, the current part 2 requirements complicate this commenter's ability to meet interoperability requirements included in the CARES Act. Under current regulations, the commenter has not released part 2 patient records, as they view the EHR as an all or nothing proposition; and consenting is unique to the patient.

Response

We acknowledge the commenter's concerns about lack of access to needed information by treating providers. As the Department stated in the 2020 final rule "[a]lthough not a defined term under part 2, a 'bona fide medical emergency' most often refers to the situation in which an individual requires urgent clinical care to treat an immediately life-threatening condition (including, but not limited to, heart attack, stroke, overdose), and in which it is infeasible to seek the individual's consent to release of relevant, sensitive SUD records prior to administering potentially life-saving care."²⁸⁸ In the 2017 final rule, the Department stated that "[w]ith regard to the request that a 'medical emergency' be determined by the treating provider, SAMHSA clarifies that any health care provider who is treating the patient for a medical emergency can make that determination."²⁸⁹ While workflow barriers may exist in particular institutions or situations during medical emergencies, patient identifying information may be disclosed to medical personnel to meet the bona fide medical emergency and support patient treatment.²⁹⁰

Comment

A medical professionals association opined that the proposed rule does not make any changes to the current part 2 exemption for medical emergencies, which states that SUD treatment records can be disclosed without patient consent in a "bona fide medical emergency." However, the commenter stated that there are both real and perceived barriers to providing emergency care and coordinating appropriate transitions of care for patients with SUD. For example, patients with SUD can have separate charts that are not visible to physical health clinicians in the EHR that could influence the acute care provided or in some instances even the existence of those behavioral health charts. When information is requested related to emergency treatment, there is often confusion about what type of information can be shared without violating part 2 requirements. Thus, in practice, when there is any amount of uncertainty, part 2 providers and physical health providers trying to provide and coordinate care that falls under part 2 revert to the most restrictive access possible even if not indicated at that time. The commenter provided another potential concern related to methadone dosing. Unless patients disclose that they are taking methadone or it is indicated in prior notes in the physical health EHR, a treating emergency physician would have no way of knowing that the patient is even taking methadone, let alone their dosage.

The commenter believed that aligning the rules governing physical health and behavioral health, as this proposed rule attempts to do, will hopefully reduce stigma and better enable emergency physicians to care for the whole individual, working in parallel with other clinicians.

Response

We acknowledge the commenter's concerns and appreciate that the aims of the changes throughout this regulation are to reduce stigma for patients with SUD and improve integrated care. Additionally, this final rule provides in § 2.12(d) that a part 2 program, covered entity, or business associate that receives records based on a single consent for all TPO is not required to segregate or segment such records, therefore more integrated care may be available for patients who sign a TPO consent.

Final Rule

The final rule adopts the proposed changes to § 2.51(c)(2) without further modification.

Section 2.52—Scientific Research Proposed Rule

Section 2.52 permits part 2 programs to disclose patient identifying information for research, without patient consent, under limited circumstances. Paragraph (a) sets forth the circumstances for when patient identifying information may be disclosed to recipients conducting scientific research. Paragraph (b) governs how recipients conducting the research may use patient identifying information. In § 2.52(b)(3), any individual or entity conducting scientific research using patient identifying information may include part 2 data in research reports only in non-identifiable aggregate form. Paragraph (c) governs how researchers may use patient identifying information to form data linkages to data repositories, including requirements for how researchers must seek Institutional Review Board approval to ensure patient privacy concerns are addressed.

The Department proposed to change the title of this section from "Research" to "Scientific Research" for consistency with 42 U.S.C. 290dd–2(b)(2)(B) that permits programs to disclose to "qualified personnel for the purpose of conducting scientific research"

The Department also proposed to change the de-identification standard in § 2.52(b)(3) to more closely align with the HIPAA Privacy Rule de-identification standard. Specifically, the current text for § 2.52(b)(3) permits a person conducting scientific research using patient identifying information that has been disclosed for research to "include part 2 data in research reports only in aggregate form in which patient identifying information has been rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder."

Consistent with proposed changes to § 2.16(a)(1)(v) and (a)(2)(vi) (Security for records and notification of breaches), discussed above, the Department proposed to modify the language in this section related to rendering information non-identifiable so that it also refers to the HIPAA Privacy Rule de-identification standard. Under our proposal, a person conducting scientific research using patient identifying information disclosed for research

²⁸⁸ 85 FR 42986, 43018.

²⁸⁹ 82 FR 6052, 6095.

²⁹⁰ 85 FR 42986, 43018; 82 FR 6052.

would have been permitted to “include part 2 data in research reports only in aggregate form in which patient identifying information has been de-identified in accordance with the requirements of the HIPAA Privacy Rule at 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder.”

As explained above in section § 2.16, section 3221(c) of the CARES Act required the Department to apply the HIPAA Privacy Rule de-identification standard for PHI codified in 45 CFR 164.514(b) to part 2 for the purpose of disclosing part 2 records for public health purposes. The change here (and in § 2.16 above) was proposed to further advance alignment with HIPAA and reduce burden on disclosing entities that would otherwise have to apply differing de-identification standards.

The Department also proposed for clarity and consistency to replace several instances of the phrase “individual or entity” with the term “person,” which would encompass both individuals and entities, and to replace the term “individual” with the term “person.”

Comment

As discussed above in connection to § 2.16, commenters that addressed de-identification largely voiced support for adopting a uniform standard in this regulation that aligns with HIPAA, including adopting a de-identification standard applicable to research data. Many of these commenters believed that doing so could facilitate alignment and understanding among covered entities and part 2 programs.

Response

The Department appreciates these comments.

Comment

One commenter questioned whether the Department should define the terms “research” and “researcher” because it is not clear how the terms apply outside a traditional academic or medical research setting. This commenter also urged the Department to clarify whether the definitions of these terms in the HIPAA Privacy Rule at 45 CFR 164.501 be used as the standard in § 2.52.

Response

We appreciate the comment and have not applied the HIPAA definitions of “research” and “researcher” with the final rule because those were not adopted by the CARES Act amendments to 42 U.S.C. 290dd–2. We acknowledge

that the HIPAA Privacy Rule definition of “research” is useful and could be applied to research using part 2 records; however, we decline in this rule to require that. Within the Privacy Rule, “research” is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”²⁹¹ The HIPAA Privacy Rule does not define the term “researcher” but in guidance the Department has explained when a researcher is considered a covered entity (“[f]or example, a researcher who conducts a clinical trial that involves the delivery of routine health care such as an MRI or liver function test, and transmits health information in electronic form to a third party payer for payment, would be a covered health care provider”).²⁹² We continue to believe that the purpose behind each term is sufficiently clear without having to incorporate regulatory terms in this part.

Comment

More than half of all commenters that expressed support for the Department’s research proposal urged the Department to expressly permit disclosure of part 2 records in limited data sets protected by data use agreements as allowed in the HIPAA Privacy Rule. These commenters asserted that doing so may greatly facilitate the exchange of public health information and research about SUDs. One commenter, a research company that expressed support for the de-identification proposal, believed that it failed to address the creation of limited data sets as defined by HIPAA, including that patient consent should not be required to create limited data sets. The commenter urged recognition in § 2.52(a) of what the commenter referred to as the “right” of part 2 programs or responsible parties conducting scientific research to use identifiable part 2 data for making de-identified data or limited data sets without the need for obtaining individual consent in the same manner as is permitted under 45 CFR 164.514.

Response

We decline to finalize a provision that would incorporate limited data sets into this regulation. We understand that

²⁹¹ 45 CFR 164.501 (definition of “Research”). The definition is based on the Common Rule definition of the same term, 45 CFR 46.102 (July 19, 2018).

²⁹² See U.S. Dep’t of Health and Human Servs., “When is a researcher considered to be a covered health care provider under HIPAA” (Jan. 9, 2023), <https://www.hhs.gov/hipaa/for-professionals/faq/314/when-is-a-researcher-considered-a-covered-health-care-provider-under-hipaa/index.html>.

commenters have questions and suggestions regarding the interaction of the HIPAA limited data set requirements and the part 2 research requirements. We did not propose any changes to this regulation to expressly address limited data sets and are not finalizing any such changes in this rule; however, we will take these comments into consideration for potential future rulemaking or guidance.

Comment

One commenter, a research association, perceived a discrepancy in how part 2 and HIPAA would treat de-identified information under the proposal. This commenter argued that under proposed § 2.52(b)(3), part 2 programs must limit the use of de-identified part 2 data in “research reports” to data presented in aggregate form instead of treating it as non-PHI as in the HIPAA Privacy Rule. The commenter asserted that this unnecessarily restricts research without benefiting patients and defeats the CARES Act objective to align part 2 with HIPAA. The commenter recommended that the Department consider alternate language in § 2.52(b)(3) such as: “[m]ay use Part 2 data in research if the patient identifying information (a) has been de-identified in accordance with any of the standards of the HIPAA Privacy Rule at 45 CFR 164.514(b); or (b) is in the format of a limited data set as defined in 45 CFR 164.514(e), which limited data set is used in accordance with all requirements of § 164.514(e), including the requirement for a data use agreement.”

Response

As stated previously, the Department did not propose to incorporate limited data sets into this regulation and is not finalizing such a change in this final rule. Additionally, the statute limits the disclosure of records in reports, not the use of records in conducting research. Section 290dd–2(b)(2)(B) of title 42 provides that records may be disclosed without consent “[t]o qualified personnel for the purpose of conducting scientific research . . . but such personnel may not identify, directly or indirectly, any individual patient in *any report* [emphasis added] of such research . . . [.]”

Comment

A few individual commenters claimed that researchers consistently demonstrate the ability to re-identify data so de-identification of SUD records offers no protection to this sensitive information and exposes patients to stigmatization.

Response

As noted above in connection to a similar comment regarding the de-identification proposal in § 2.16, the Department is aware of the concerns related to the potential to re-identify data. The Department, however, also recognizes that the HIPAA standard for de-identification incorporated here is largely viewed as workable and understandable. We believe this sentiment is borne out in the much larger set of supportive comments.

Final Rule

Similar to the approach adopted in § 2.16 (Security for records and notification of breaches), above, the final rule incorporates the HIPAA Privacy Rule de-identification standard at 45 CFR 164.514(b) into § 2.52 as proposed, and further modifies this section to more fully align with the complete HIPAA de-identification standard that adopts and includes language from 45 CFR 164.514(a). The final rule deletes the phrase in § 2.52(b)(3), “as having or having had a substance use disorder,” and modifies this language to: “such that there is no reasonable basis to believe that the information can be used to identify a patient.” In so doing, we are aligning with the HIPAA standard in paragraph (a) of 45 CFR 164.514 which refers to “no reasonable basis to believe that the information can be to identify an individual,” and is not limited to removing information about a particular diagnoses or subset of health conditions. In this way, the final standard incorporated here is more privacy protective than the proposed standard. Moreover, as we also stated in connection with the final de-identification standard incorporated in § 2.16 above, our adoption of the same de-identification standard for public health disclosures (new § 2.54) into this provision provides a uniform method for de-identifying part 2 records for all purposes. Finally, we removed the language “the HIPAA Privacy Rule” from regulatory references to 45 CFR 164.514(b) because we believe it to be unnecessary.

Section 2.53—Management Audits, Financial Audits, and Program Evaluation

Proposed Rule

The Department proposed to change the heading of § 2.53 to specifically refer to management audits, financial audits, and program evaluation to more clearly describe the disclosures permitted without consent under 42 U.S.C. 290dd–2(b)(2)(B). The Department also

proposed to replace several instances of the phrase “individual or entity” with the term “person”, which would encompass both individuals and entities. The Department also proposed to modify the audit and evaluation provisions at § 2.53 by adding the term “use” where the current language of § 2.53 refers only to disclosure and by adding paragraph (h) (Disclosures for health care operations).

Section 2.53 permits a part 2 program or lawful holder to disclose patient identifying information to an individual or entity in the course of certain Federal, State, or local audit and program evaluation activities. Section 2.53 also permits a part 2 program to disclose patient identifying information to Federal, State, or local government agencies and their contractors, subcontractors, and legal representatives when mandated by law if the audit or evaluation cannot be carried out using de-identified information.

The Department explained in the NPRM that there is significant overlap between activities described as “audit and evaluation” in § 2.53 and health care operations as defined in the HIPAA Privacy Rule at 45 CFR 164.501. For example, the following audit and evaluation activities under part 2 align with the health care operations defined in the HIPAA Privacy Rule, as cited below:

- Section 2.53(c)(1) (government agency or third-party payer activities to identify actions, such as changes to its policies or procedures, to improve care and outcomes for patients with SUDs who are treated by part 2 programs; ensure that resources are managed effectively to care for patients; or determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD);²⁹³
- Section 2.53(c)(2) (reviews of appropriateness of medical care, medical necessity, and utilization of services);²⁹⁴ and
- Section 2.53(d) (accreditation).²⁹⁵

In addition, activities by individuals and entities (“persons” under the final rule) conducting Medicare, Medicaid, and CHIP audits or evaluations described at § 2.53(e) parallel those defined as health oversight activities in the HIPAA Privacy Rule at 45 CFR 164.512(d)(1). Part 2 programs and lawful holders making disclosures to these persons must agree to comply with all applicable provisions of 42

U.S.C. 290dd–2, ensure that the activities involving patient identifying information occur in a confidential and controlled setting, ensure that any communications or reports or other documents resulting from an audit or evaluation under this section do not allow for the direct or indirect identification (e.g., through the use of codes) of a patient as having or having had an SUD, and must establish policies and procedures to protect the confidentiality of the patient identifying information consistent with this part. Patient identifying information disclosed pursuant to § 2.53(e) may be further redisclosed to contractor(s), subcontractor(s), or legal representative(s), to carry out the audit or evaluation, but are restricted to only that which is necessary to complete the audit or evaluation as specified in paragraph (e).²⁹⁶

We confirm here that nothing in the proposed or final rule is intended to alter the existing use and disclosure permissions for the conduct of audits and evaluations, including for investigative agencies that conduct audits. Thus, an investigative agency that is performing an oversight function may continue to review records under the § 2.53 requirements as they did under the previous rule. At such time within a review that an audit needs to be referred for a criminal investigation or prosecution, that investigative agency would be expected to follow the requirements under subpart E for seeking a court order. In the event an investigative agency fails to seek a court order because it is unaware that it has obtained part 2 records, it may rely on the newly established safe harbor within § 2.3, provided that it first exercised reasonable diligence in trying to ascertain if the provider was providing SUD treatment. In making use of the safe harbor, an investigative agency would then be obligated to follow the new requirements in § 2.66 or § 2.67, as applicable.

Section 3221(b) of the CARES Act amended the PHSA to permit part 2 programs, covered entities, and business associates to use or disclose the contents of part 2 records for TPO after obtaining the written consent of a patient.²⁹⁷ Covered entities, including those that are also part 2 programs, and business associates are further permitted to redisclose the same information in accordance with the HIPAA Privacy Rule. As the Department noted throughout the NPRM, these new

²⁹³ See, e.g., 45 CFR 164.501 (definition of “Health care operations,” paragraph (5)).

²⁹⁴ See, e.g., 45 CFR 164.501 (definition of “Health care operations,” paragraph (1)).

²⁹⁵ See, e.g., 45 CFR 164.501 (definition of “Health care operations,” paragraph (2)).

²⁹⁶ See 42 CFR 2.53(e)(6).

²⁹⁷ Codified at 42 U.S.C. 290dd–2(b)(1)(B).

disclosure pathways are permissive, not required.

To implement the new TPO permission that includes the ability of the entities above to use or disclose part 2 records for health care operations with a general consent, the Department proposed to modify the audit and evaluation provisions at § 2.53 by adding the term “use” where the current language of § 2.53 refers only to disclosure and by adding paragraph (h) (Disclosures for health care operations). This new paragraph as proposed would clarify that part 2 programs, covered entities, and business associates are permitted to disclose part 2 records pursuant to a single consent for all future uses and disclosures for TPO when a requesting entity is seeking records for activities described in paragraph (c) or (d) of § 2.53. Such activities are health care operations, but do not include treatment and payment. To the extent that a requesting entity is itself a part 2 program, covered entity, or business associate that has received part 2 records pursuant to a consent that includes disclosures for health care operations, it would then be permitted to redisclose the records for other purposes as permitted by the HIPAA Privacy Rule. Thus, if an auditing entity is a part 2 program, covered entity, or business associate that has obtained TPO consent and is not performing health oversight, it would not be subject to all the requirements of § 2.53 (*e.g.*, the requirement to only disclose the records back to the program that provided them). Requesting entities that are not part 2 programs, covered entities, or business associates would not have this flexibility but would still use existing permissions in § 2.53 to obtain access to records for audit and evaluation purposes, and they would remain subject to the redisclosure limitations and written agreement requirement therein.

The Department proposed paragraph (h) which would leave intact existing disclosure permissions and requirements for audit and evaluation activities without consent, including health care oversight activities, such as described in paragraph (e). At the same time, the proposal would provide a new mechanism for programs and covered entities to obtain patient consents for all future TPO uses and disclosures (including redisclosures), which in some instances may include audit and evaluation activities.

Comment

We received several comments about audit and evaluation provisions. Most commenters expressed support for our

proposed changes to this section. A major health plan expressed support without further comment. Others expressed support and offered additional recommendations or suggestions for further alignment or clarity. A state data center requested clarity on whether there could be other permissible disclosures for licensing proceedings and hearings before an administrative tribunal brought by an agency that provides financial assistance to the part 2 program or is authorized by law to regulate the part 2 program and administratively enforce remedies authorized by law to be imposed as a result of the findings of the administrative tribunal. The commenter suggested adding a new subsection § 2.53(c)(3) to address these issues and add appropriate restrictions.

One state regulatory agency expressed concerns about § 2.53 describing its recent experience with licensed health care facilities significantly disrupting the department's regulatory responsibilities by using 42 CFR part 2 as justification. Specifically, it expressed concern that licensed health care facilities may rely on the proposed public health authority exception to prevent the state from accessing SUD records without patient consent or a court order. This same agency further commented that the final rule should clarify the scope of the “public health authority” exception and affirm the ability of state licensing authorities to access identifiable patient records pursuant to § 2.53 for surveys and investigations.

Response

We appreciate the comments on our proposed changes. We discuss redisclosure provisions in § 2.33. We clarify here that although the new disclosure permission for public health in § 2.54 is limited to records that are de-identified, the existing permission for access to identifiable patient information in § 2.53 remains a valid and viable means for government agencies with audit and evaluation responsibilities to review records without obtaining a court order. We believe that Congress enacted the public health disclosure permission to enhance the ability of part 2 programs and other lawful holders of part 2 records to report to public health authorities. This is distinct from the regulatory and oversight authority over programs and lawful holders that permits them to review records that are not de-identified, providing the conditions of § 2.53 are met. We decline to add a new subsection to § 2.53(c) to clarify other disclosure provisions for use by

regulatory agencies with enforcement authority over part 2 programs and lawful holders, but §§ 2.62, 2.63, 2.64, and 2.66 may govern use of audit and evaluation records in criminal and non-criminal proceedings against a program. These provisions also are clear that a court order will not be granted unless other means of obtaining the records are unavailable or would be ineffective. Therefore, use of the disclosure permission under § 2.53 is encouraged as courts are unlikely to grant these orders given the provisions of this rule.

Comment

Several commenters addressed APCDs or MPCDs. One non-profit agency which administers a state-based APCD commented that the rule should expressly include a permission to disclose to state-mandated APCDs for audit and evaluation purposes required by statute or regulation. It also recommended that the Department clarify that a state mandated APCD housed in a non-state nonprofit entity does not need to be providing oversight and management of a part 2 program as a prerequisite for relying on § 2.53 to conduct an audit or evaluation on behalf of a state agency. It asserted that in many states the APCD is the most comprehensive source of cross-payer data and analytics, and the lack of clarity around APCD authority to hold SUD data is actively hampering the ability to use APCDs to provide information about the current opioid epidemic, to evaluate what and where progress is being made, and to determine if there are populations with inequitable access to the programs and mitigation strategies used across the country. Another non-government agency and a state agency made similar comments and a recommendation for guidance or an express permission to disclose SUD records to a state agency for APCDs.

One commenter remarked that there continues to be confusion within the data submitter community about the ability of health insurance carriers to legally submit data to state health database organizations without patient consent. According to the commenter, there is an opportunity for the Department to expressly identify this use as an authorized release of data to state agencies. Alternatively, the Department could provide guidance for the existing rules with this necessary clarification rather than use the rule-making process. The commenter also suggested that HHS provide clarification to understand better if the limitations in § 2.53(f) apply to audits/evaluations

conducted under all of § 2.53 or only those preceding § 2.53(f).

A state agency recommended that restrictions against law enforcement accessing the database and against information in the databases being used for legal proceedings against the patient should accompany the permission to disclose to state APCDs. It further requested clarity on whether it has authority to request SUD data from downstream HIPAA covered entities (such as health plans and non-part 2 providers) and business associates if those entities received part 2 records for TPO purposes with patient consent. The commenter also opined that although, by law, it receives data to determine what actions are needed at a health plan level to improve care and outcomes for patients in part 2 programs, it was not clear if the limitations in § 2.53(f) prohibited another state agency also conducting mandated audit or evaluations under § 2.53(g) from providing or sharing that data. If not, the state agency noted government agencies may not be able to “directly use” its databases, even if they are conducting proper but separate audit or evaluations under § 2.53. Such a result, according to the commenter, could result in lost efficiencies and added burdens on part 2 programs or lawful holders because they would need to provide the data to the requesting government agencies, instead of the government agencies utilizing existing state databases. The commenter also asserted that per § 2.53(g), this data release would only occur in cases where the work could not be carried out using de-identified information (and subject to the government agency recipient accepting privacy and security responsibilities consistent with applicable law).

Response

We appreciate the comments on APCDs or MPCDs and other provisions under this section and may provide additional guidance after this rule is finalized. In preamble to the 2017 Part 2 Final Rule, the Department stated “that MPCDs [. . .] are permitted to obtain part 2 data under the research exception provided in § 2.52, provided that the conditions of the research exception are met. Furthermore, an MPCD [. . .] that obtains part 2 data in this fashion would be considered a ‘lawful holder’ under these final regulations and would therefore be permitted to redisclose part 2 data for research purposes, subject to the other conditions imposed under § 2.52.”²⁹⁸

In the preamble to the 2020 Part 2 Final Rule, the Department explained that under § 2.53, government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving care and outcomes for part 2 patients.²⁹⁹ Such purposes could include, *e.g.*, provider education and recommending or requiring improved health care approaches.³⁰⁰ The Department also noted that government agencies and private not-for-profit entities granted authority under applicable statutes or regulations may be charged with conducting such reviews for licensing or certification purposes or to ensure compliance with Federal or state laws. The 2019 Part 2 NPRM explained “that the concept of audit or evaluation is not restricted to reviews that examine individual part 2 program performance.”³⁰¹

In this final rule we also provide in this section that a part 2 program, covered entity, or business associate may disclose records in accordance with a consent that includes health care operations to the extent that the audit or evaluation constitutes a health care operation activity, and the recipient may redisclose such records as permitted under the HIPAA Privacy Rule if the recipient is a covered entity or business associate. Health care operations include a broad range of quality improvement and related activities, some of which overlap with the audit and evaluations under § 2.53.³⁰²

As worded, § 2.53(f) applies to the entirety of § 2.53 and states that “[e]xcept as provided in paragraph (e) of this section, patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained and may be used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66.”

Comment

One managed care entity asserted that the proposed rule should fully align the part 2 audit and evaluation provisions with the HIPAA Privacy Rule to avoid

distinctions between disclosures that would be permitted as part of health care operations but might not fit within the scope of audits and evaluations. It further commented that such misalignment could be administratively challenging and inadvertently impact the results of audits and evaluations due to incomplete or inaccurate data sets.

A large pharmacy provider commented that it strongly supported alignment of HIPAA and 42 CFR part 2, and to achieve full alignment, the Department should clarify that HIPAA governs all part 2 records that are PHI when in the hands of covered entities and business associates for any TPO purposes, including not applying the audit and evaluation provisions of § 2.53 to covered entities when the subject activities fall within TPO for HIPAA purposes. A major health system commented that the redisclosure permission granted to part 2 providers, covered entities, and business associates for records received under a TPO consent (including for the clarified health care operations provision at § 2.53) may lead to better SUD treatment and payment for such treatment, and a reduction of operational issues between and among providers and their business associates.

Response

The changes to § 2.53 as finalized more closely align with the HIPAA Privacy Rule because this section now expressly addresses disclosures for health care operations that are permitted with a single consent for all future uses and disclosures for TPO under §§ 2.31 and 2.33. However, full alignment of § 2.53 with the HIPAA Privacy Rule is not authorized by the CARES Act because most of this section includes additional protections for part 2 records when used or disclosed for oversight, such as vesting the part 2 program director with discretion to determine whether a requester is qualified, prohibiting redisclosure of the records by the recipient, and requiring the return or destruction of records after completion of the audit and evaluation. We address redisclosures in more depth in the discussion of § 2.32 and TPO disclosures in § 2.33 above.

Comment

Although the CARES Act does not expressly address § 2.53, one commenter believed that leaving out health oversight activities while including the CARES Act provisions for TPO purposes makes SUD patients more vulnerable. This individual commenter further suggested that the general regulatory authority given to the

²⁹⁹ 85 FR 42986, 43023.

³⁰⁰ *Id.*

³⁰¹ 85 FR 42986, 43023; 84 FR 44568, 44579.

³⁰² See “Uses and Disclosures for Treatment, Payment, and Health Care Operations,” *supra* note 248.

²⁹⁸ 82 FR 6052, 6102.

Department by the CARES Act would permit incorporating health oversight into this provision, which the commenter views as an acceptable tradeoff for diminished patient autonomy in terms of consent.

Response

Even though section 3221(e) of the CARES Act does not expressly address audits and evaluations, 42 U.S.C. 290dd–2 continues to reference audits and evaluations. The CARES Act emphasized use and disclosure of records for TPO and restrictions on use and disclosure in civil, criminal, administrative, or legislative proceedings. We note and have discussed in the 2018 and 2020 final rules³⁰³ and 2022 NPRM that § 2.53 is comprised of many activities that many would view as constituting health care oversight, including audits and quality improvement activities. Paragraph (e) specifically concerns Medicare, Medicaid, CHIP, or related audit or evaluation. In addition, § 2.62 expressly precludes records that are obtained under this section from being used and disclosed in proceedings against the patient.

Final Rule

The final rule adopts the proposed changes to § 2.53, with two modifications to paragraph (h). The first is to limit redisclosure to recipients that are covered entities and business associates and the second is to refer to “HIPAA regulations” instead of 45 CFR 164.502 and 164.506. We believe this is consistent with the changes to § 2.33(b) and the addition of the defined term “HIPAA regulations.”

Section 2.54—Disclosures for Public Health

Proposed Rule

The existing part 2 regulations do not permit the disclosure of part 2 records for public health purposes. Section 3221(c) of the CARES Act added paragraph (b)(2)(D) to 42 U.S.C. 290dd–2 to permit part 2 programs to disclose de-identified health information to public health authorities and required the content of such de-identified information to meet the HIPAA Privacy Rule de-identification standard for PHI codified in 45 CFR 164.514(b). Accordingly, the Department proposed to add a new § 2.54 to permit part 2 programs to disclose part 2 records without patient consent to public health authorities provided that the information is de-identified in

accordance with the standards in 45 CFR 164.514(b).

We proposed this change in conjunction with 42 U.S.C. 290dd–2(b)(2)(D), as added by CARES Act section 3221(d), which directed the Department to add a new definition of “public health authority” to this part. We also proposed the new definition in § 2.11, as discussed above.

Comment

Most commenters voiced support for the proposal to permit disclosures of de-identified records to public health authorities. Comments included assertions that the proposal may: promote awareness of SUDs; align goals between providers and public health authorities regarding SUD treatment; better help address the drug overdose crisis by ensuring information was available to develop useful tools while not impinging on individuals’ privacy; assist with addressing population health matters; improve population health; and assist vulnerable populations by ensuring SUD records are available (*e.g.*, addressing the COVID–19 pandemic).

Response

The Department appreciates the comments and takes the opportunity to reiterate here that the proposal is consistent with the new authority enacted in the CARES Act.

Comment

Some commenters asserted that while the regulation should allow the disclosure of SUD records for public health purposes, it should permit the disclosure of identifiable information rather than limit it to de-identified data. A few of these commenters acknowledged that the CARES Act modified title 42 to permit disclosure only of health information de-identified to the HIPAA standard in 45 CFR 164.512(b). Despite awareness of the CARES Act, these commenters gave multiple reasons why they thought the Department should promulgate a rule that permits the disclosure of identifiable data to a public health authority. For example, several of these commenters, including an academic medical center, a private SUD recovery center, and a state-affiliated HIE, asserted that state laws often require public health reporting for communicable/infectious disease surveillance. A Tribal consulting firm asserted that part 2 rules for disclosing data to public health authorities contradict state, Tribal, local, and territorial public health laws when other health care providers are required to submit individually identifiable

information. A SUD treatment provider cited the potential vulnerability of this patient population to sexually transmitted diseases and the need for individual level data (*e.g.*, age, address) to accomplish effective disease surveillance and resource allocation. A managed care organization, a health system, and a few state/local health departments commented that the limitation of disclosing only de-identified information could hinder public health efforts. A few HIE/HINs commented that in their role as Health Data Utilities, they regularly share critical health data with public health authorities. They gave examples such as overdose death information, which facilitates public health authorities’ provision of appropriate follow-up services and resources to those affected by SUD. The HIE/HINs also have a role in producing public and population health information such as data maps or other rendering showing utilization of SUD facilities and open bed counts for the purpose of referrals. These organizations commented that the differences between HIPAA and the proposed part 2 public health disclosure permission may complicate the IT landscape.

Response

We acknowledge the many good explanations of how identifiable information could be useful for public health purposes that would not involve public reporting of patient identifying information. However, we lack authority to permit disclosures of identifiable information for public health purposes absent patient consent. This limitation is reflected in the amended statute at 42 U.S.C. 290dd–2(b)(2)(D).

Comment

Several other commenters supported the proposal but suggested other modifications or accompanying guidance. For example, one commenter, a regional HIN, asserted that part 2 and HIPAA already permit the disclosure of de-identified data without patient consent, and therefore the revision is a clarification rather than a substantive change. It urged the Department to clarify that the use of a general designation on an authorization form could allow disclosures to public health authorities operating in their state of residence. It also requested the Department to clarify—either in regulation or in guidance—when disclosures to public health authorities may fall into the research or audit and evaluation consent exceptions. A major health plan commented that conducting public health activities using a limited

³⁰³ See 83 FR 239, 247 and 85 FR 42986, 43025, respectively.

data set would be more useful and could advance important public health goals, as de-identified data lacks dates of service and ages which are often important variables for both research and public health activities. A state commented that the Department should specify what constitutes “public health purposes.” A large health care provider commented that the Department could help clarify the general right to de-identify part 2 records and disclose such de-identified part 2 records by including an explicit right to do so in the regulations as a permitted use, including an express right to use part 2 records for health care operations and to create a de-identified data set without patient consent.

Response

We appreciate these comments but have proposed this provision consistent with statutory authority. With respect to limited data sets, we address this topic in the discussion of § 2.52 above. We decline at this time to issue guidance related to distinctions between public health activities, research activities, and audit and evaluation. We have not received a large number of comments or requests to do so but will monitor for the need to address once this rule is finalized.

Comment

A health information management organization opposed the proposal and commented that the Department should fully understand the realities of de-identified data and should engage patient advocacy focused organizations to understand if transmitting de-identified data to public health entities would jeopardize patient trust in part 2 programs. It further commented that the de-identification standard for data within health care continues to evolve and change overtime as technology and artificial intelligence is better able to reidentify patients.

Response

The CARES Act now requires the Department to finalize a standard that permits disclosure of information that is de-identified according to the HIPAA standard. Although we are obligated to implement the standard, we will monitor developments in accepted de-identification practices and how emerging technology developments may reduce the effectiveness of current standards.

Comment

One commenter, a health system, recommended that the Department ensure the de-identification standard for

records conforms with various state reporting requirements and patient expectations. It cited the example of the state being required to track and report certain statistical information. The commenter also believed that adopting the HIPAA standard should be done in a way to allow for continued compliance with these state regulations. Another commenter, a medical professionals association, urged the Department to facilitate coordination between physicians and health IT entities to improve de-identification technology and make it more widely accessible for physician practices. A few other commenters, another medical professional association and a trade association representing health plans, commented that it was important for best practices for de-identification to be adhered to and reflected in regulations, and that regulated entities should specify which de-identification methods are being used for each data set.

Response

We have found that in most cases, state reporting requirements contemplate the disclosure of aggregate data, which may include de-identified records. Similarly, our authority to override state public health report requirements is statutorily limited. We express support for and encourage physicians to work with their respective technology vendors to assure the availability of compliant technology in physician practices.

Final Rule

The final rule adopts the proposed addition of a new § 2.54 into this regulation, and the accompanying definition of “public health authority” discussed in § 2.11. The proposal is adopted with further modification, but we believe it remains within our authority as enacted by the CARES Act. Consistent with the approach adopted above in §§ 2.16 (Security for records and notification of breaches) and 2.52 (Scientific research), we are further modifying the language proposed to align with the full HIPAA de-identification standard, which includes 45 CFR 164.514(a). As such, the final standard here permits a part 2 program to disclose records for public health purposes if made to a “public health authority” and the content has been de-identified in accordance with the requirements of the HIPAA Privacy Rule standard at 45 CFR 164.514(b), “such that there is no reasonable basis to believe that the information can be used to identify a patient.” This final language strikes from the proposal the limiting phrase after this language that

is in the existing rule: “as having or having had a substance use disorder.” In addition, we removed the language “the HIPAA Privacy Rule” from the regulatory reference to 45 CFR 164.514(b) because we believe it unnecessary.

We reiterate here that the proposed change should not be construed as extending the protections of part 2 to de-identified information, as such information is outside the scope of § 2.12(a). Thus, once part 2 records are de-identified for disclosure to public health authorities, part 2 no longer applies to the de-identified records.

Subpart E—Court Orders Authorizing Use and Disclosure

The CARES Act enacted significant statutory changes governing how records could be used in legal proceedings. Section 290dd–2(c) (Use of Records in Criminal, Civil, or Administrative Contexts), as amended by section 3221(e) of the Act, newly emphasizes the allowance of written consent as a basis for disclosing records for proceedings. Revised paragraph (c) of 42 U.S.C. 290dd–2, as amended, now provides “[e]xcept as otherwise authorized by a court order under subsection (b)(2)(c) or by the consent of the patient, a record referred to in subsection (a), or testimony relaying the information contained therein, may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings [. . .] against a patient [. . .].” Thus, paragraph (c) of the amended statute also applies restrictions beyond records to “testimony relaying the information contained therein.” In the NPRM, the Department proposed to implement this amended statutory provision across every subpart E section as applicable, and in addition, proposed changes to §§ 2.12(d) and 2.31, discussed above, to more generally address how restrictions on use and disclosure of records apply in legal proceedings, and requirements for the structure of written consents for uses and disclosures of record and information in testimony in legal proceedings.³⁰⁴

³⁰⁴ As discussed above, the Department is finalizing changes to § 2.12, Applicability. Paragraph (d) of § 2.12, as finalized, provides that restrictions on the use and disclosure of any record to initiate or substantiate criminal charges against a patient or to conduct any criminal investigation of a patient, or to use in any civil, criminal, administrative, or legislative proceeding against a patient, applies to any person who obtains the record from a part 2 program, covered entity, business associate, intermediary, or lawful holder regardless of the status of the person obtaining the record or whether the record was obtained in accordance with part 2.

To properly reflect that subpart E regulates uses and disclosures of records, information, and testimony therein, the Department is finalizing the proposed heading so that it now refers to “Court Orders Authorizing Use and Disclosure.” We received no comments addressing the proposed change in heading. We also note with respect to proposed modifications throughout this subpart, many public comments were intermingled across sections or intended to provide comment related to multiple regulatory sections. To the best of our ability, we responded to such comments in the regulatory section where we believe them most applicable.

Section 2.61—Legal Effect of Order

Section 2.61 includes the requirement that in addition to a court order that authorizes disclosure, a subpoena is required to compel disclosure of part 2 records. The final rule adopts the proposed addition to add the word “use” to paragraphs (a) and (b)(1) and (2) to clarify that the legal effect of a court order with respect to part 2 records would include authorizing the use of part 2 records, in addition to the disclosure of part 2 records. The Department did not propose substantive changes to this section although in relation to other provisions of this rulemaking, a few commenters expressed concern that the rule contemplates the added expense of a subpoena. Those comments are addressed below.

Section 2.62—Order Not Applicable to Records Disclosed Without Consent to Researchers, Auditors, and Evaluators Proposed Rule

Section 2.62 provides that a court order issued pursuant to part 2 may not authorize “qualified personnel” who have received patient identifying information without consent for conducting research, audit, or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. As we explained in the NPRM, the term “qualified personnel” has a precise meaning but does not have a regulatory definition within 42 CFR part 2 and is used only once within the regulation. For greater clarity, the Department proposed to refer instead to “persons who meet the criteria specified in § 2.52(a)(1)(i) through (iii),” and later in the paragraph to “such persons.” The individual paragraphs of § 2.52(a)(1)(i) through (iii) describe the circumstances by which the person designated as director, managing director, or authoritative representative of a part 2

program or other lawful holder may disclose patient identifying information to a recipient conducting scientific research.

Comment

The Department did not receive comments specific to this section.

Final Rule

The Department adopts the proposed change and additionally inserts “and § 2.53” as a technical correction given that the regulatory text references audit and evaluation but not § 2.53. The final text provides that the court “may not authorize persons who meet the criteria specified in §§ 2.52(a)(1)(i) through (iii) and 2.53, who have received patient identifying information without consent for the purpose of conducting research, audit, or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient.”

Section 2.63—Confidential Communications

Proposed Rule

Section 2.63 contains provisions that protect the confidential communications made by a patient to a part 2 program. Paragraph (a) of § 2.63 provides that a court order may authorize disclosure of confidential communications made by a patient to a part 2 program during diagnosis, treatment, or referral only if necessary: (1) to protect against an existing threat to life or of serious bodily injury; (2) to investigate or prosecute an extremely serious crime, such as one that directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or (3) in connection with litigation or an administrative proceeding in which the patient introduces their own part 2 records. Paragraph (b) of current § 2.63 is reserved.

To implement changes to 42 U.S.C. 290dd–2 that could properly be applied to this section, the Department proposed to specify in § 2.63(a)(3) that civil, as well as criminal, administrative, and legislative proceedings are circumstances under which a court may authorize disclosures of confidential communications made by a patient to a part 2 program. Specifically, the Department proposed in § 2.63(a)(3) to expand the permission’s application from “litigation or administrative proceeding” to “civil, criminal, administrative, or legislative proceeding” in which the patient offers testimony or other evidence pertaining

to the content of the confidential communications.

Comment

One commenter expressed support for the proposal with the caveat that the part 2 program or covered entity be permitted to use the records, without a requirement that the patient first introduce the records into a legal proceeding, if the purpose of the use is for defense against professional liability claims brought by the patient.

One health plan also expressed unconditional support for this proposal.

Response

We appreciate the comments. We reaffirm here that this regulation is intended to protect those communications that are narrow in scope and limited to those statements made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment. We believe continuing to permit disclosure only under circumstances of serious harm coupled with a patient’s own “opening the door” in legal proceedings strikes the right balance against an obvious disincentive to seeking care when such communications are not kept confidential. On the other hand, should an applicant believe it necessary to seek a court order and subpoena authorizing and compelling disclosure, respectively, there is nothing in this section that would restrict the ability of the applicant to attempt to convince a court that the information sought is broader than that governed by § 2.63, such as information contained in records subject to disclosure under § 2.64 and evaluation by a competent court with jurisdiction.

Final Rule

The final rule adopts the proposed changes to this section without further modification.

Section 2.64—Procedures and Criteria for Orders Authorizing Uses and Disclosures for Noncriminal Purposes

Proposed Rule

Section 2.64 describes the procedures and criteria that permit any person having a legally recognized interest in the disclosure of patient records for purposes “other than criminal investigation or prosecution” to apply for a court order authorizing the disclosure of the records.

The current language of § 2.64 refers only to “purposes other than criminal investigation or prosecution” and “noncriminal purposes” in the heading. To implement the changes to 42 U.S.C. 290dd–2(c), the Department proposed to

modify paragraph (a) of § 2.64 to expand the forums for which a court order must be obtained, absent written patient consent, to permit use and disclosure of records in civil, administrative, or legislative proceedings. The Department also proposed, consistent with the language of the amended statute, to apply the requirement for the court order to not only records, but “testimony” relaying information within the records.

Comment

One commenter, a state Medicaid Office, sought guidance from the Department on determining the appropriateness of applying redisclosure procedures under HIPAA or part 2 when the underlying disclosure relates to a judicial or administrative proceeding. Specifically, this commenter noted that following a receipt of records pursuant to a TPO consent, proposed § 2.33(b) authorizes subsequent redisclosures under HIPAA regulations. As an example, it described a covered entity that receives an order for part 2 records of a Medicaid recipient as part of a civil, administrative, legislative, or criminal proceeding or criminal investigation. The proceeding in this situation is not against the Medicaid recipient who is instead, a witness, an alternate suspect, or other third-party individual. In these cases, this commenter asked if it should review and respond to the order under 45 CFR 164.512(e) ³⁰⁵ pursuant to the proposed § 2.33(b) or under the procedures required by § 2.64.

Response

As we understand the commenter’s example and question, the underlying proceedings are not against the subject of the records or “patient,” and therefore the covered entity would be permitted to redisclose the records in accordance with the HIPAA Privacy Rule permission at 45 CFR 164.512(e). This response is consistent with the part 2 statute and with revised § 2.33(b) which provides that “[i]f a patient consents to a use or disclosure of their records consistent with § 2.31, the recipient may further use or disclose such records as provided in subpart E of this part, and as follows . . . [w]hen disclosed for treatment, payment, and health care operations activities [. . .] the recipient may further use or disclose those records in accordance with the HIPAA regulations, except for uses and disclosures for civil, criminal,

administrative, and legislative proceedings *against the patient* [emphasis added].”

Although revisions to § 2.33 permit a covered entity or business associate to redisclose records obtained pursuant to a TPO consent “in accordance with the HIPAA regulations,” any person seeking to redisclose such records or information in a proceeding against the patient is required to comply with the procedures in § 2.64 or § 2.65 to obtain the part 2 court order or a separate consent of the patient that meets the requirements of new § 2.31(d).

Comment

One supportive commenter, a health system, asserted that a reasonable and necessary exception to the rule requiring patient consent or court order is in the case of a health care entity and provider needing access to records to vigorously defend their positions in legal proceedings against a patient, such as with a professional liability claim. This commenter further asserted that redacted records would be inadequate for preparation or case presentation.

Response

We do not believe that a professional liability claim brought by a patient against a provider is a proceeding “against a patient.” If a provider believes that a part 2 record or information is required to mount a defense against a professional liability claim brought by a patient, there is nothing in this regulation which would prevent the provider from seeking relief from a court.

Comment

One commenter did not object to the Department’s proposal extending the current provision to apply to administrative and legislative proceedings, but objected to the requirement that a part 2 program or covered entity may incur legal expenses to obtain an instrument that would compel compliance (*i.e.*, a subpoena, in addition to a court order).

Response

We appreciate the comment but even before this rulemaking, § 2.61 made clear that the sole purpose of a court order issued pursuant to subpart E was to authorize use or disclosure of patient information but not to compel the same. Additionally, under the current § 2.61, a subpoena or a similar legal mandate must be issued in order to compel disclosure. There is nothing in the CARES Act amendments that suggests we should modify these requirements.

Comment

Several commenters expressed support for this proposal, including a county department of public health and several individuals. One individual expressed strong support for restricting disclosures for civil and non-criminal procedures to promote racial equity. Another individual commenter thanked the Department for protecting patients from having records used against them, including the content of records in testimony.

Response

We appreciate the comments, but historically part 2 has always placed some restriction on disclosure of records in both civil and criminal types of proceedings.

Final Rule

The final rule adopts § 2.64 as proposed in the NPRM without further modification.

Section 2.65—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Criminally Investigate or Prosecute Patients

Proposed Rule

Section 2.65 establishes procedures and criteria for court orders authorizing the use and disclosure of patient records in criminal investigations or prosecutions of the patient. Under § 2.65(a), the custodian of the patient’s records or a law enforcement or prosecutorial official responsible for conducting criminal investigative or prosecutorial activities, may apply for a court order authorizing the disclosure of part 2 records to investigate or prosecute a patient. Paragraph (b) describes the operation of notice to the holder of the records about the application for a court order under this section and opportunity to be heard and present evidence on whether the criteria in paragraph (d) for a court order have been met. Paragraph (d) sets forth criteria for the issuance of a court order under this section, including paragraph (d)(2), which requires a reasonable likelihood that the records would disclose information of substantial value in the investigation or prosecution. Paragraph (e) sets forth requirements for the content of a court order authorizing the disclosure or use of patient records for the criminal investigation or prosecution of the patient. Paragraph (e)(1) requires that such order must limit disclosure and use to those parts of the patient’s record as are essential to fulfill the objective of the order, and paragraph (e)(2) requires that the order limit the disclosure to those law enforcement and

³⁰⁵ 45 CFR 164.512(e) grants permissions to covered entities to disclose PHI for judicial and administrative proceedings.

prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigating and prosecuting extremely serious crimes or suspected crimes specified in the application.³⁰⁶ Paragraph (e)(3) requires that the order include other measures as are necessary to limit use and disclosure to the fulfillment of only that public interest and need found by the court.

The Department proposed to modify § 2.65 (a) to expand the types of criminal proceedings related to the enforcement of criminal laws to include administrative and legislative criminal proceedings for which a court order is required for uses and disclosures of records, and in paragraphs (a), (d) introductory text, (d)(2), (e) introductory text, and (e)(1) and (2), to include testimony relaying information within the records. The Department also proposed a non-substantive change to move the term “use” before “disclosure” in paragraphs (e) introductory text and (e)(1) and (3). As noted in the NPRM, criminal investigations may be carried out by executive agencies and legislative bodies as well as in criminal prosecutions through the judicial process. These changes implement 42 U.S.C. 290dd–2(c), as amended by section 3221(e) of the CARES Act by widening the scope of confidentiality protections for patients in all of these forums where an investigation or action may be brought against them.

Notably, the statute, as amended by the CARES Act, also expressly permits disclosures and uses of records and testimony in legal proceedings against the patient if a patient consents. To address concerns about consent for use and disclosure of records in proceedings against the patient, the Department is adding a separate consent requirement in § 2.31(d), as discussed above.

Comment

Nearly half of all commenters that addressed subpart E proposals opposed the proposal to allow patients to consent to the use and disclosure of their part 2 records in proceedings against the patient. Many of these commenters contended that permitting disclosures of records and testimony in proceedings

against the patient, based on the patient’s consent, only makes patients vulnerable to coercion from law enforcement who condition certain outcomes in the matter underlying the dispute on obtaining consent.

While several commenters acknowledged the statutory language that expressly allows consent for court proceedings, most nonetheless urged the Department not to implement the statutory change and instead finalize a regulatory provision that will protect patients from law enforcement seeking to condition outcome in criminal and civil proceedings on signed consent forms. Other commenters expressed alarm that the consent provision would further disincentivize historically vulnerable populations experiencing SUD, including pregnant individuals, from seeking SUD treatment. One commenter asserted that recipients of records released with consent for criminal, civil, administrative, and legislative proceedings are lawful holders under the regulations and recommended they be expressly barred from using these records or patient information in ways that discriminate against the patient.

Response

We appreciate the sentiments expressed by many of these commenters regarding the risks of a consent option. However, the language of the statute, as amended by the CARES Act, is clear and unambiguous and emphasizes the existing ability of patients to consent to the use or disclosure of their records or testimony within such records in legal proceedings against them. We also view patient consent as one of the cornerstones of privacy protection. Consistent with the statute and principle of empowering the patient to control the flow of their own information, the existing rule at § 2.33(a) clearly allows patient consent for disclosure of records for any purpose, which may include investigations and proceedings against the patient. The final rule expands this to encompass consent for use of records as well as disclosures. Additionally, in §§ 2.12 and 2.31 above, we discuss the specific regulatory modifications that refer to consent for legal proceedings and newly require separate consent for use and disclosure of records in civil, criminal, administrative, and legislative proceedings. We reiterate here that we intend for references to such proceedings to also encompass investigations, as stated in 42 U.S.C. 290dd–2.

Comment

One commenter, a mental health advocacy organization, commented that the Department should establish a safe harbor that would protect health plans from civil and criminal penalties when violations arise from good faith redisclosures that comply with the HIPAA Privacy Rule but not part 2. According to this commenter this provision could support sharing information on claims databases since there are disparate state approaches to protecting and administering these records.

Response

We are sympathetic to concerns related to disparate state laws that conflict with or overlap with this Part, and understand the issues faced by plans that consistently interact with or disclose information to state claims databases. However, we believe the extent of our statutory authority is clear in how this regulation only permits use and disclosures of records and information therein, in legal proceedings against patients, when consent or the requisite court order is obtained. Having said that, under the newly promulgated enforcement structure required by statute, criminal liability inures only when a willful or knowing violation occurs. Moreover, the crux of this requirement remains as it did prior to this rulemaking and the CARES Act did nothing to modify the added protection afforded to records that would otherwise be used to prosecute a patient. Given the continuity of this requirement, we anticipate that plans and state claims databases should have already built-in mechanisms to accommodate this regulation.

Comment

Approximately one-third of commenters on this topic supported requiring patient consent or a court order for use and disclosure of part 2 records against a patient or a part 2 program. Some of these commenters expressed appreciation for the expanded protection from use and disclosure in legislative and administrative investigations and proceedings, and express protection of testimony that conveys information from part 2 records within the consent or court order requirements. Some commenters expressed the sentiment that these express and expanded protections would serve as a counterweight to easing the flow of part 2 records for health care-related purposes.

³⁰⁶ Section 2.63(a)(1) and (2) of the current rule specifies that the type of crime for which an order to disclose confidential communications could be granted would be one “which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect.” Thus, the use of an illegal substance does not in itself constitute an extremely serious crime.

Response

We appreciate these comments. As we've stated above, the revised language of this section, and our revision to § 2.12(d), discussed above, implement key CARES Act statutory modifications. We agree that the expanded protections for testimony arising from information contained in records, and the extension of protection to additional types of legal proceedings could counterbalance, in some respects, the expanded permission to use and disclose of part 2 records under a single consent for all future TPO.

Comment

One commenter, a health system, expressed support for this proposal but suggested that a covered entity should be able to rely and act upon a court order issued by a court of competent jurisdiction without potentially incurring additional legal expenses for an instrument compelling compliance.

Response

Consistent with our response above, the requirement for a subpoena has been firmly enshrined in part 2 and was not proposed for revision in this rulemaking.

Comment

An individual appreciated the emphasis in the § 2.65 NPRM discussion that “the use of an illegal substance does not in itself constitute an extremely serious crime” and recommended reiterating that neither substance use nor engagement in SUD treatment services should in and of themselves be considered evidence of child abuse or neglect, including for people who are pregnant.

Response

We agree and state that the regulation continues to place emphasis on crimes that pose threats to loss of life or serious bodily injury, such as homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.³⁰⁷

Final Rule

The final rule adopts § 2.65 as proposed without further modification.

³⁰⁷ See §§ 2.65(d)(1) (criteria for court issuance of an order authorizing use and disclosure of records in a criminal proceeding against a patient) and 2.63(a)(2) (limiting disclosure of confidential communications to investigations or prosecution of serious crimes).

Section 2.66—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Investigate or Prosecute a Part 2 Program or the Person Holding the Records

Proposed Rule

The Department proposed to add a new paragraph (a)(3) that details procedures for investigative agencies to follow in the event they unknowingly obtain part 2 records during an investigation or prosecution of a part 2 program or person holding part 2 records without obtaining a court order as required under subpart E. Section 2.66 specifies the persons who may apply for an order authorizing the disclosure of patient records for the purpose of investigating or prosecuting a part 2 program or “person holding the records (or employees or agents of that part 2 program or person holding the records)” in connection with legal proceedings, how such persons may file the application, and provides that, at the court's discretion, such orders may be granted without notice to the part 2 program or patient.

In conjunction with a new definition of “investigative agency” that the Department proposed and is finalizing in § 2.11 above, the Department modified paragraph (a) to refer only to “investigative agency” as the type of organization that may apply for an order under this section. The new term includes, by definition, the other types of organizations referenced in the current provision (*i.e.*, state or Federal administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of part 2 programs or other person holding part 2 records) as well as local, Tribal, and territorial agencies. The Department also proposed a new paragraph (a)(3). The Department's proposed change would require an investigative agency (other than one relying on another disclosure provision, such as § 2.53(e))³⁰⁸ that discovers in good faith that it has obtained part 2 records to secure the records consistent with § 2.16 and immediately cease using or disclosing them until it obtains a court order

³⁰⁸ Section 2.53 also permits a person to disclose patient identifying information for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation. However, subpart E proceedings are distinguished from those under § 2.53 in that § 2.53 audits and evaluation are limited to that conducted by a governmental agency providing financial assistance to a part 2 program or other lawful holder or an entity with direct administrative control over the part 2 program or lawful holder, and is determined by the part 2 program or other lawful holder to be qualified to conduct an audit or evaluation. See § 2.53 for the provision in its entirety.

authorizing the use and disclosure of the records and any records later obtained. A court order must be requested within a reasonable period of time, but not more than 120 days after discovering it received the records. As proposed, if the agency does not seek a court order, it must return the records to the part 2 program or person holding the records if it is legally permissible to do so, within a reasonable period of time, but not more than 120 days from discovery; or, if the agency does not seek a court order or return the records, it must destroy the records in a manner that renders the patient identifying information non-retrievable, within a reasonable period of time, but not more than 120 days from discovery. Finally, if the agency's application for a court order is rejected by the court and no longer subject to appeal, the agency must return the records to the part 2 program or person holding the records, if it is legally permissible to do so, or destroy the records immediately after notice of rejection from the court.

The Department proposed in paragraph (b) to provide an option for substitute notice by publication when it is impracticable under the circumstances to provide individual notification of the opportunity to seek revocation or amendment of a court order issued under § 2.66. Additionally, the Department proposed to reorganize paragraph (c) by expressly incorporating the provisions from § 2.64(d)³⁰⁹ that would require an applicant to obtain a good cause determination from a court and adding the proposed § 2.3(b) requirements as elements of good cause for investigative agencies that apply for a court order under proposed § 2.66(a)(3)(ii).

We note at the outset of the discussion of comments for this section and § 2.67 that some comments were intertwined with comments in response to § 2.3(b), limitation of liability for investigative agency personnel. Those comments are addressed above in the discussion of comments related to § 2.3(b).

Comment

A large health system expressed support for providing a remedy when an investigative agency discovers in good faith that it has received part 2 records, that allows the agency to either seek a court order or return records in lieu of an order.

³⁰⁹ In addition to incorporating the provisions in § 2.64(d), the Department proposed a slight modification to § 2.66(c)(1) to add that other ways of obtaining the information would yield incomplete information.

Response

We appreciate the comments.

Comment

Several commenters, including a Medicaid fraud unit and a large health system, expressed support for the proposal to allow for substitute notice under § 2.66 when individual notice is infeasible or impractical. One commenter, a state-based regional Medicaid fraud unit, asked the Department to consider applying the “substitute notice by publication” requirement retroactively.

Response

We appreciate the comments regarding substitute notice. In consideration of the burden that would inure to part 2 programs and holders of records, we decline to make this requirement retroactive.

Comment

A state Medicaid fraud unit recommended that it not be considered an “investigative agency” as defined in § 2.11 and used in this section and § 2.67, and that it be permitted to access records without a court order. In the alternative, it expressed support for the proposed safe harbor and related procedures proposed in §§ 2.66 and 2.67.

Response

We believe that a state Medicaid fraud unit meets the definition of “investigative agency” in § 2.11. The definition that we are finalizing provides that “[i]nvestigative agency means a Federal, state, Tribal, territorial, or local administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding part 2 records.” We are aware that in some states, Medicaid fraud units are created within state attorney general offices under Federal authority.³¹⁰

Comment

A commenter, a state-based data center requested that language be added to § 2.66(a)(2), (b), and (c) to clarify that an administrative tribunal can issue orders under this section, and that a separate court proceeding is not required.

Response

As we have noted previously, we lack authority to circumvent the statutory

requirement in 42 U.S.C. 290dd–2(c) for a court order to authorize use and disclosure of records for civil, criminal, administrative, and legislative proceedings, including administrative tribunals.

Comment

One commenter, a managed care organization, requested that the Department require investigative agencies to notify the program when it unknowingly is in receipt of part 2 records but lacks the required court order and whether it intends to seek a court order, return, or destroy the records. The organization also requested clarification that the rule does not authorize an investigative agency to destroy records unless it has confirmed that they are not originals.

Response

We believe the proposed rule adequately protects the records from misuse by requiring the person holding the records to either return the records in a timely manner or destroy the records in a manner that renders the patient identifying information non-retrievable in a timely manner. We do not believe additional notice to the part 2 program or other holder of the record, as described by this commenter, is necessary and believe such a notice would go beyond the current rule in § 2.66 which does not require notice to be made until such time as a court order is granted. We agree that it is a best practice to confirm with the part 2 program that produced the records whether they are originals before an investigative agency destroys them.

Comment

One commenter, a state Medicaid agency recommended that the Department include language outlining what “good faith” means and what will happen if the standard is not met.

Response

We believe it unnecessary to define in regulation the phrase “good faith,” which is required to support a finding that an investigative agency unknowingly acquired part 2 records in the course of an investigation in § 2.66, § 2.67, or a finding that the safe harbor applies to shield from liability investigators who are holding such records.³¹¹ We believe the phrase is

generally understood to mean without malice or without bad intent. We also believe that the operation of this provision is clear, in the event a finding of good faith is not met. First, if investigators are found to have acted in bad faith in obtaining the part 2 records, penalties could result. Second, in §§ 2.66 and 2.67, a finding of good faith is necessary to trigger the ability of the agency to apply for a court order to use records that were previously obtained.

Comment

One commenter, an advocacy organization, requested that additional protections be added to § 2.66 (as well as § 2.3) for cloud service providers (CSPs). Such protections, the commenter believed, would apply to a “person holding the record” who coordinates with the SUD data owner (to the extent permitted by the legal request) and, despite such coordination unknowingly makes a record available in response to an investigatory court order or subpoena. This same commenter further requested that the Department allow CSPs to, at their discretion: (1) require requestors of records to certify or attest that, to the best of the requestor’s knowledge, part 2 records are not part of the request or that information sought will not be used as part of proceedings against a patient of a part 2 program; and (2) rely on such certifications or attestations of requestors when making disclosures in response to an investigatory court order or subpoena.

Response

We understand the challenges faced by CSPs and agree that under some circumstances they may be treated as the “person holding the record” under this regulation. However, under many service agreements the person that stores data in a CSP system is the one with the legal capability to disclose the data. We decline to adopt additional rules for CSPs that are different than the rules for other lawful holders of a part 2 record. The rule does not prevent a person holding the record to inquire of the requestor whether they have knowledge as to the nature of the records within the scope of the request. However, we believe that a holder of the record, as a baseline, has some responsibility to know whether they are maintaining records that are PHI or subject to part 2. We also believe that in most cases, a CSP should be acting under the purview of a valid business associate agreement or other contract that specifies the particular protections

³¹⁰ See, e.g., Maryland Office of the Att’y Gen., “Medicaid Fraud Control Unit,” <https://www.marylandattorneygeneral.gov/Pages/MFCU/default.aspx>.

³¹¹ See our NPRM discussion at 87 FR 74216, 74227 where we stated, “The proposed safe harbor could promote public safety by permitting government agencies to investigate or prosecute Part 2 programs and persons holding Part 2 records for suspected criminal activity, in good faith without risk of HIPAA/HITECH Act penalties.”

needed with respect to the type of data being held and disclosed.³¹²

Comment

One commenter, a medical professionals association, expressed concern that the patient notification process is insufficient (including under existing policies). In particular, according to this commenter the notification process may be problematic for those patients who lack mailing addresses, and it is not clear that the allowance for substitute notice by publication would increase its effectiveness. Instead, this commenter recommended instituting further notice requirements such as more detailed information provided to part 2 patients regarding the potential for court-ordered disclosure of records, the absence of an initial notice requirement, and the potential for substitute notice by publication. This same commenter recommended such information be included in the HIPAA NPP and included on the part 2 program's website; further, if a part 2 program comes under investigation and receives a court order authorizing disclosure, the part 2 program be required to post information on its website regarding the investigation and court order.

Response

We assume the crux of this comment is that the proposal does not account for an initial notice to a patient upon an application for a court order by a person seeking to use or disclose the patient's record. We disagree that the regulation does not provide for adequate notice to patients and part 2 programs about the entry of court orders. With respect to patients, we have proposed and are finalizing in a revised Patient Notice required by § 2.22 a requirement that part 2 programs include in the Patient Notice a statement such as “[r]ecords shall only be used or disclosed based on a court order after notice and an opportunity to be heard is provided to the patient or the holder of the record, where required by 42 U.S.C. 290dd–2 and this part”. We believe this statement provides adequate notice to the patient such that the patient is made aware that he or she will be provided

with some type of notice in the event a court order authorizes a use or disclosure of the patient's records. As we have stated above, the HIPAA Privacy Rule proposed modifications and public comments will be considered in a separate rulemaking.

While we agree with the sentiment that website notice of a court ruling permitting use or disclose of a patient's records is generally reasonable, we decline to adopt this as a regulatory requirement. Given the court involvement in these proceedings, we believe it best left to the discretion of the court to determine the means of substitute notice that is reasonable under the specific circumstances that exist at the time.

Comment

One individual expressed negative views about this section and opined that the Department's proposed new paragraph § 2.66(a)(3) is not related to any requirement in the CARES Act. It is instead, according to this commenter, a means to excuse efforts by investigative agencies that fail to presume, as they should, that an investigation of a part 2 program would result in obtaining part 2 records. This commenter further recommended that the investigative agency be required to seek court authorization prior to any investigation and that the good faith standard is “disingenuous.” Finally, this commenter opined that the proposed option in § 2.66(b) for a substitute notice by publication when it is deemed “impracticable” under the circumstances to provide individual notification of the opportunity to seek revocation or amendment of a court order runs counter to the protection of patients in that an ability to locate a patient should not diminish their right to confidentiality.

Response

We understand the underlying concerns expressed in this comment and in response, are making some additional modifications to the proposed rule as discussed below. Also, in response, we point to the robust requirements that relate to obtaining the court order under paragraph (c) of this section, including that other ways of obtaining the information are not available (or would not be effective or would yield incomplete results), there is a public interest that outweighs potential injury to the patient, and the required diligence that must be exercised on the part of the investigative agency related to determining the application of this part. Additionally, with respect to substitute notice, it is

only permitted once it is determined that individual notice is not available. Further, we assume that agencies obtaining a court order under § 2.66 have already complied with the requirement to use a pseudonym for the patient in the application for the court order (or to ensure the court seals the record of the proceedings) and expect them to comply with the requirement not to disclose any patient identifying information in any public mention of the court order, which would include any public form of substitute notice.

Final Rule

We are appreciative of the many comments in response to this section, but as we note above, the requirement of a court order or consent to make uses and disclosures regulated under this section has not changed, despite the widening of application to types of proceedings and testimony contained in records. In addition, as proposed, this change is consistent with the revised statute. The final rule therefore adopts § 2.66 as proposed with one additional modification. We are modifying paragraph (c)(3) to clarify that with respect to an application pursuant to § 2.66(a)(3)(ii), it is not permissible to use information from records obtained in violation of part 2 to support an application for a court order under 42 U.S.C. 290dd–2(b)(2)(C). We adopted this modification in response to commenters' concerns about the potential misuse of the safe harbor established in § 2.3(b) by investigative agencies. We are adding this express prohibition on the use of records obtained in violation of part 2 to counterbalance the latitude provided to investigative agencies and to disincentivize improper uses of information to support applications for court orders.

Section 2.67—Orders Authorizing the Use of Undercover Agents and Informants To Investigate Employees or Agents of a Part 2 Program in Connection With a Criminal Matter

Proposed Rule

Section 2.67 authorizes the placement of an undercover agent in a part 2 program as an employee or patient by law enforcement or a prosecutorial agency pursuant to court order when the law enforcement organization has reason to believe the employees of the part 2 program are engaged in criminal misconduct. Paragraph (a) authorizes the application of an order by law enforcement or prosecutorial agencies for placement of undercover agents or informants in part 2 program based on

³¹² See U.S. Dep't of Health and Human Servs., “Guidance on HIPAA & Cloud Computing” (Dec. 23, 2022), <https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/cloud-computing/index.html> (“The BAA also contractually requires the business associate to appropriately safeguard the ePHI, including implementing the requirements of the Security Rule.” From an enforcement standpoint, we would apply this same principle to any agreement between a CSP and originator of part 2 data under part 2 obligations.).

reason to believe criminal activity is taking place. Paragraph (c) includes the “good cause” criteria by which an order under this section may be entered.

The Department proposed to replace the phrase “law enforcement or prosecutorial” with “investigative” in paragraph (a), and clarify that the good cause criteria for a court order in paragraph (c)(2) includes circumstances when obtaining the evidence another way would “yield incomplete evidence.” The Department also proposed to create a new paragraph (c)(4) addressing investigative agencies’ retroactive applications for a court order authorizing placement of an undercover informant or agent to investigate a part 2 program or its employees when utilizing the safe harbor under § 2.3. This provision would require the investigative agency to satisfy the conditions at proposed § 2.3(b) before applying for a court order for part 2 records after discovering that it unknowingly had received such records.

Comment

Several commenters, including a large health system and managed care organization, expressed support for the requirement that an investigative agency placing an undercover agent or informant must seek a court order and promote strict adherence to the requirements, including limitations and restrictions on uses and disclosures of part 2 information, of the court order. One of the commenters asserted that, if finalized, the proposal may ensure appropriate conduct by local and state agencies.

Response

We appreciate the comments.

Comment

One commenter, a regional state-based Medicaid fraud unit, recommended that the Department define or issue guidance about the meaning of “yield incomplete evidence.”

Response

Paragraph (c)(3) addresses one of the criteria under which a court must make a good cause determination for the entry of an order permitting placement of an undercover agent by an investigative agency, and requires a finding that other ways of obtaining information are not available or would “yield incomplete evidence.” We believe the court evaluating the application of this criteria is best situated to determine the facts and whether said facts support this finding.

Comment

An individual commenter expressed strong concern that proposed § 2.67 represents an unnecessary concession to law enforcement. Citing what this individual believes to be a prior concession in the 2020 rulemaking related to an extension of time from six to twelve months in which an undercover agent could be placed in a part 2 program,³¹³ this commenter expressed the belief that this proposal relies on a second concession, grounded in “convenience” for law enforcement that uses the “good cause” criteria for a court order in paragraph (c)(2) as a justification circumstance when obtaining the evidence another way would “yield incomplete evidence.” This commenter specifically objected to modifying the current in paragraph (c)(2) by adding “or would yield incomplete evidence” after “other ways of obtaining evidence of the suspected criminal activity are not available or would not be effective.”

Response

We appreciate the sentiment expressed in this comment, but believe that the newly imposed statutory civil penalties require us to consider, and finalize, a more workable standard for law enforcement. We also believe that the commenter fails to appreciate the difficulty in determining at times whether a health care entity has records that are subject to part 2. The need for a means for law enforcement to investigate crimes related to activity by part 2 programs or their employees remains a reality, as does the need to keep sensitive records confidential. Overall, we believe that because the standard applied will be adjudicated by a court of competent jurisdiction from which appeals may be taken, the modified criteria is appropriate.

Final Rule

The final rule adopts § 2.67 as proposed with one additional modification to paragraph (c)(4) to clarify that with respect to an application submitted after the placement of an undercover agent or informant has already occurred, the applicant is prohibited from using information from records obtained in violation of part 2 by that undercover agent or informant. We adopt this modification in response to those public comments expressing concern about the potential for misuse of the limitation on liability established in § 2.3(b) to persons who under the purview of investigative agencies, are granted safe

harbor for unknowingly and in good faith obtaining part 2 records. Similar to our consideration of comment in response to § 2.66, we believe the express prohibition on the use of records obtained in violation of part 2 will disincentivize improper uses of information to support applications for court orders.

Section 2.68—Report to the Secretary Proposed Rule

The Department proposed to create a new § 2.68 to require investigative agencies to file an annual report with the Secretary of the applications for court orders filed after obtaining records in an investigation or prosecution of a part 2 program or holder of records under § 2.66(a)(3)(ii) and after placement of an undercover agent or informant under § 2.67(c)(4). The report as proposed would also include the number of instances in which such applications were denied due to findings by the court of violations of this part during the calendar year, and the number of instances in which the investigative agency returned or destroyed part 2 records following unknowing receipt without a court order, in compliance with § 2.66(a)(3)(iii), (iv), or (v), respectively during the calendar year. The Department proposed that such reports would be due within 60 days following the end of the calendar year. The comments and the Department’s responses regarding § 2.68 are set forth below.

Comment

A state government asserted that requiring investigative agencies to file an annual report of the number of applications for court orders, the number of requests for court orders denied, and the number of instances of records returned following unknowing receipt without a court order could be extremely time consuming and unduly burdensome. Further, according to this commenter, calendar year reporting of this data does not align with Federal and state fiscal year reporting causing additional burden on investigative agencies.

Response

We appreciate the comment. An investigative agency should file a court order in advance of receiving part 2 records or placing an undercover agent or informant in a part 2 program in accordance with §§ 2.66 and 2.67, respectively. A report is only required for investigative agencies that discover in good faith that they received part 2 records that required a court order in

³¹³ 85 FR 42986, 43039.

advance and a court order was not initially sought. Additionally, we did not receive data in public comments from investigative agencies about how frequently this occurs, and we will monitor this requirement after the final rule to gain an understanding of how widespread these retroactive discoveries are. To limit the burden, the Department has made this an annual report, rather than per incident reporting, with 60 days to compile the data after the end of the calendar year. And the calendar year reporting aligns with the HIPAA breach reporting requirements for breaches of unsecured PHI affecting fewer than 500 individuals. Also, the Federal, state, and local fiscal year reporting dates may differ across jurisdictions, and it is not feasible for the Department to align all reporting dates.

Comment

The Department received a few supportive comments about the benefits to the annual reporting requirement which may include: assuring appropriate conduct by local and state investigative agencies; assuring ongoing compliance; auditing the use of the limitation on liability within this regulation; and promoting the privacy and security of part 2 information.

Response

We appreciate the comments.

Comment

One commenter asked: (1) how the Department will advise Federal, state, and local law enforcement about the requirement to submit annual reports; (2) what the consequences of failing to submit an annual report will be; (3) what the purpose is and what criteria the Department will apply; and (4) how the Department will use the information in the annual reports to safeguard patient privacy rights and improve law enforcement's understanding of the rule.

Response

We appreciate the comment. A report is only required for investigative agencies that discover in good faith that they have received part 2 records for which a court order was required in advance and that a court order was not initially sought. We do not have data on how frequently this occurs and one purpose of the requirement is to gain an understanding of how widespread these retroactive discoveries are. The consequences of failing to meet the reporting requirement are the same as for other violations of the part 2 rule under the newly established penalties which utilize the four culpability tiers

that are applied to HIPAA violations; however, part 2 programs, covered entities, and business associates that create or maintain part 2 records are the primary focus of this regulation. In determining compliance with the safe harbor reporting requirement, the Department would focus on an investigative agency rather than an employee of that agency. The Department will provide guidance or instructions on how to submit the reports to the Secretary on its website and through press releases and OCR listserv announcements.³¹⁴ The reporting obligation is not intended to be a public reporting requirement, but for the Department's internal use in evaluating the utility and effectiveness of the safe harbor provision in § 2.3. The Department will review the annual reports and consider what guidance or other resources are needed by investigative agencies that are lawful holders of part 2 records.

Final Rule

The final rule adopts the proposed language of new § 2.68, without modification.

Re-Ordering "Disclosure and Use" to "Use and Disclosure"

Proposal

The Department proposed throughout the NPRM to re-order the terms "disclosure and use" in the part 2 regulation to "use and disclosure."³¹⁵ The new order of these terms is consistent with their usage in the HIPAA Privacy Rule which generally regulates the "use and disclosure" of PHI and relies on the phrase as a term of art.³¹⁶

Comment

The Department received no substantive comments other than a few commenters that expressed general support for re-ordering terms to align with the HIPAA Privacy Rule.

Final Rule

The final rule adopts each proposal to re-order these terms,³¹⁷ although not

³¹⁴ OCR has established two listservs to inform the public about health information privacy and security FAQs, guidance, and technical assistance materials. To sign up for the OCR Privacy & Security Listserv, visit: <https://www.hhs.gov/hipaa/for-professionals/list-serve/index.html>.

³¹⁵ See 87 FR 74216, 74225, fn 109.

³¹⁶ Consistently, the Department refers to "uses and disclosures" or "use and disclosure" in the HIPAA Privacy Rule. See, e.g., 45 CFR 164.502 Uses and disclosures of protected health information: General rules.

³¹⁷ See final regulatory text for § 2.2(a)(2) and (3) and (b)(1); § 2.12(c)(5) and (6); § 2.13(a) and (b); § 2.21(b); § 2.34(b); § 2.35(d); § 2.53(a), (b)(1)(iii),

discussed in detail here. As stated in the NPRM, we believe these changes fall within the scope of our regulatory authority and further the intent and implementation of the CARES Act by improving the ability of regulated entities to use and disclose records subject to protection by part 2 and HIPAA.

Inserting "Use" or "Disclose" To Reflect the Scope of Activity

Proposal

The Department also proposed to add the term (or related forms of the term) "use" where only the term "disclose" was present in the part 2 regulation or in some cases the term "disclose" (or related forms) where only the term "use" was present.³¹⁸ This proposed change was intended to more accurately describe the scope of the activity that is the subject of the regulatory provision. In the NPRM, the Department described these changes as non-substantive, but we did receive comments opining in some instances that adding the term "use" in particular, changes the scope of part 2. We also explained in the NPRM that we believe these changes are necessary to align with changes made to 42 U.S.C. 290dd–2(b)(1)(A), as amended by section 3221(b) of the CARES Act (providing that part 2 records may be used or disclosed in accordance with prior written consent); to 42 U.S.C. 290dd–2(b)(1)(B) and (b)(1)(C), as amended by section 3221(b) of the CARES Act (providing that the contents of part 2 records may be used or disclosed by covered entities, business associates, or part 2 programs as permitted by the HIPAA regulations for TPO purposes); and to 42 U.S.C. 290dd–2(c), as amended by section 3221(e) of the CARES Act (prohibiting disclosure and use of part 2 records in proceedings against the patient).

Overview of General Comments

The Department requested comment on these proposed modifications and received generally supportive or positive comments in response. Several commenters suggested the Department go further than the proposed changes and the proposed definition of "use" by adopting the HIPAA definitions of "use" and "disclosure" to further align part 2 with the HIPAA regulations. A few HIE associations indicated that they did not believe that the addition of "use" or "uses" to existing regulatory text would substantively expand the

(e)(1)(iii), (e)(6), (f); subpart E heading; § 2.61(a); § 2.62; § 2.65 heading, (a), (d), (e) introductory text, and (e)(1) and (3); § 2.66 heading, (a)(1), and (d).

³¹⁸ See 87 FR 74216, 74225, fn 111.

scope of requirements and prohibitions where previously the text stated only “disclosure.” One commenter stated the addition of “use” or “uses” may actually narrow the scope for which part 2 data can be obtained, as disclosure does not require the implication that the data is being used for TPO and could just be held by an entity. A state agency said that it would not anticipate adverse consequences to part 2 programs or to its own operations from the revisions throughout the rule that add the terms “use” or “uses” to references to “disclose” or “disclosure.”

A health plan said that these changes may limit confusion around obligations with respect to “use” and “disclose.” The plan said that these words are often considered terms of art in contracts and other privacy-related policies and documents. As such, clarifying when requirements apply to either or both terms by re-ordering or adding such terms to provisions may help covered entities and their business associates better understand their regulatory requirements under a final rule.

Another health plan supported these changes asserting that with this understanding, a part 2 record could be both used and disclosed for purposes related to the provision of care, but also for purposes such as the initiation of a legal proceeding. This change, the commenter said, can be supported by revising the definition within the HIPAA regulations.

An advocacy organization agreed with the Department that these changes are not substantive in nature, given that under part 2 and HIPAA, “use” and “disclosure” can be mutually exclusive, independent actions, and that the proposed definition of “use” is inclusive of the historical definition of “use” related to legal proceedings under part 2. A provider said this change adds clarity and better aligns the proposed rule with HIPAA terminology.

A health IT vendor had no concerns with expanding the focus of the part 2 regulations to make reference to uses in addition to disclosures in the regulatory text in a manner consistent with the HIPAA Privacy Rule construction for how uses and disclosures are defined and used throughout the HIPAA Privacy Rule. The commenter opined that part 2 regulations have not addressed the uses of SUD records for purposes within part 2 programs as they have focused on how disclosure and redisclosure of part 2 records must be handled. However, the proposed changes seem appropriate to this commenter for purpose of parallel structure and regulatory consistency between part 2 and the HIPAA Privacy Rule.

A provider contended that this change is necessary and within the Department’s regulatory authority, even if not expressly included in the CARES Act. A health system characterized this proposal as a good basic change that sets the stage for several other proposed changes toward meeting the goal of aligning with HIPAA. This change also may help reduce the existing differences in describing how we manage and protect our patient’s health information, across service locations.

Comment on Specific Sections

- A few commenters expressed support for proposed changes to replace the phrase “disclosure and use” by re-ordering the phrase to “use or disclosure” at § 2.2(a) introductory text, (a)(4), and (b)(1), to align the language with that used in the HIPAA Privacy Rule.
- A health plan expressed support for proposed changes to § 2.13 for adding the term “use” to clarify that confidentiality restrictions and safeguards apply to both uses and disclosures.
- A few commenters expressed support for adding the term “disclosure” to § 2.23.

Response

We appreciate the comments about these changes. We decline to adopt the HIPAA formal definitions for the terms “use” or “disclosure” or change the definitions of the terms in the HIPAA Privacy Rule as we believe their application is understood as applied to part 2 records and PHI, respectively. The overall sentiment of the comments is that these modifications bring clarity and the understanding about how the terms are used across the two regulations. The Department disagrees with the suggestion that adding the term “use” in some cases may narrow the scope of activity under part 2. In no regulatory provision are we changing the term “disclose” to “use” and we remind stakeholders that many TPO activities contemplate “uses.”

Overview of Final Rule

The final rule adopts all proposed modifications to add the term “use” or some form of it or “disclose” or some form of it to the scope of certain covered activities under part 2. The Department also defines the term “use” in regulation (discussed above in § 2.11).³¹⁹ As

discussed in the NPRM, historically, the part 2 regulation associated “use” with the initiation of legal proceedings against a patient and associated “disclosure” with sharing records to an external entity. In contrast, the HIPAA Privacy Rule applies the term “use” to refer to internal use of health information within an entity, such as access by staff members.³²⁰ The part 2 and HIPAA definitions for the term “disclose” are fairly consistent³²¹ and therefore a part 2 record can be both used and disclosed for purposes related to the provision of health care and for purposes such as the initiation of a legal proceeding. Where made, these changes are also consistent with section 3221(b) of the CARES Act that addresses permissions and restrictions for both uses and disclosures of records for TPO purposes by part 2 programs and covered entities, and proscribes the rules related to certain legal proceedings.

Antidiscrimination Protections, Stigma and Discrimination

Overview

As noted in the NPRM and above, paragraph (g) of section 3221 of the CARES Act, *Antidiscrimination*, adds a new provision (i)(1) to 42 U.S.C. 290dd–2 to prohibit discrimination against an individual based on their part 2 records. We stated in the NPRM and reiterate that the Department intends to develop a separate rulemaking to implement the CARES Act antidiscrimination prohibitions. Nonetheless, we received several comments on antidiscrimination requirements as well as more general concerns about stigma and discrimination. While these comments are outside the scope of this rulemaking, we briefly summarize and respond to these comments below.

Comments and Response

Comments we received on antidiscrimination issues addressed such topics as:

- Antidiscrimination rulemaking
- Harmful consequences to patients
- Increased reluctance to enter SUD treatment
- Stigma and discrimination in the context of criminalization and racial disparities
- Statistics on stigma and discrimination

and (b); § 2.34 heading; subpart D heading; § 2.52(a); § 2.53(a)(5); § 2.61(a) and (b)(1) and (2); § 2.64 heading, (a), (d)(2), and (e); § 2.65(a), (d) introductory text, (d)(2), (e) introductory text, (e)(1) and (2); § 2.66(d)(2); § 2.67(d)(3) and (e).

³²⁰ 87 FR 74232.

³²¹ 42 CFR 2.11, definition of “Disclose.” 45 CFR 160.103, definition of “Disclosure.”

³¹⁹ See final regulatory text of: § 2.2(a)(2) and (3) and (b)(1); § 2.12(a)(1) and (2), (c)(3) and (4), (d)(2) and (3), (e)(3); § 2.13(a); § 2.14(a) and (b); § 2.15(a)(2) and (b); § 2.17(b); § 2.20; § 2.23 heading and (b); subpart C heading; § 2.31(a) introductory text and (a)(4)(ii)(B); § 2.32(a)(2); § 2.33 heading, (a),

- Unwillingness to disclose SUD treatment
- Timing of SUD treatment regulatory framework
- Considering stigma in regulatory updates

Most commenters also addressed issues other than antidiscrimination topics and their comments on other provisions of part 2 were fully considered along with other comments received to the NPRM docket.

Some commenters, including medical professionals associations, advocacy organizations, a trade association, a government agency, a provider-other, a health system, SUD providers, a consultant, a researcher, a law enforcement organization, and individuals urged the Department to expedite the rulemaking implementing the CARES Act antidiscrimination protections, or to put this rulemaking on hold until the antidiscrimination protections are in place. Some commenters such as SUD providers, recovery organizations, individuals, and advocacy organizations also expressed concern about significant stigma associated with SUD and SUD treatment. Several commenters, including advocacy organizations, a professional association, a government agency, and a health plan, cited reports, survey results, and statistics they believed reflect the stigma associated with addiction that continues to influence the perceptions and behaviors of health care professionals and continues to influence patients to avoid SUD treatment.

Commenters described the many potential adverse outcomes that they say privacy protections help prevent, including discrimination in child custody, denial of life insurance, loss of employment, discrimination in health care decision making, and criminal charges, among many others. Some commenters also asserted that under the current regulations there are patients that are unwilling to disclose SUD treatment to caregivers or unwilling to enter treatment due to the concern surrounding stigma and discrimination.

Several commenters, including a mental health provider, medical professionals' associations, and a few individuals, suggested that the proposed rule may increase the reluctance of patients to seek help for SUD. Commenters pointed to such potential issues as patients being unsure of how information will be used or having SUD information used against them. Additionally, several commenters, including an advocacy organization, and individual commenters addressed the

effects of stigma and discrimination related to SUD and SUD treatment in the context of criminalization and racial disparities.

Response

We acknowledge and appreciate comments asking us to expedite promulgation of the required antidiscrimination provisions and raising concerns about the continued impacts of discrimination and stigma within health care and other settings. As noted, we intend to issue a separate proposed regulation for part 2 antidiscrimination provisions after this rule is finalized. For that reason, as detailed in the NPRM, we also decline to hold publication of this rule until the antidiscrimination provisions also are proposed and finalized. As explained, comments on the NPRM concerning antidiscrimination requirements are beyond the scope of this rulemaking. However, we will take all comments received into account as we issue the forthcoming antidiscrimination provisions of part 2. We further encourage these commenters and others to provide input on the forthcoming proposed rule containing the antidiscrimination provisions.

V. Regulatory Impact Analysis

A. Executive Orders 12866 and 13563 and Related Executive Orders on Regulatory Review

The Department has examined the impact of the final rule as required by Executive Order (E.O.) 12866 on Regulatory Planning and Review as amended by E.O. 14094, 58 FR 51735 (October 4, 1993); E.O. 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); E.O. 13132 on Federalism, 64 FR 43255 (August 10, 1999); E.O. 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (November 9, 2000); the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 847 (March 29, 1996); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (March 22, 1995); the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (September 19, 1980); E.O. 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (August 16, 2002); the Assessment of Federal Regulations and Policies on Families, Public Law 105–277, sec. 654, 112 Stat. 2681 (October 21, 1998); and the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995).

E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of E.O. 12866 (as amended by E.O. 14094) defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this E.O., as specifically authorized in a timely manner by the Administrator of OIRA in each case.

This final rule is partially regulatory and partially deregulatory. The Department estimates that the effects of the final rule for part 2 programs would result in new costs of \$26,141,649 within 12 months of implementing the final rule. The Department estimates these first-year costs would be partially offset by \$13,421,556 of first year cost savings, attributable to reductions in the need for part 2 programs to obtain written patient consent for disclosures for treatment, payment, or health care operations (TPO) (\$10.3 million); reductions in the need for covered entities, business associates, and part 2 programs to obtain written patient consent for redisclosures (\$2.6 million); and reductions in capital expenses for printing consent forms (\$0.5 million). This results in an estimated net cost of \$12,720,093 in the first year of the rule. This is followed by net savings of approximately \$5.2 to \$5.4 million annually in years two through five, resulting from a continuation of first-year cost saving of \$13.4 million per year, minus varying Federal costs at approximately \$2.3 to \$2.6 million in years 1 to 5 and the estimated annual

costs of \$5.7 million primarily attributable to compliance with attaching consent forms with every disclosure and breach notification requirements. This results in overall net cost savings of \$8,445,536 over 5 years for changes to 42 CFR part 2.

The Department estimates that the private sector would bear approximately 60 percent of the costs, with state and Federal health plans bearing the remaining 40 percent of the costs. All of the cost savings experienced from the first year through subsequent years would benefit part 2 programs and covered entities. This final rule is a significant regulatory action, under sec. 3(f) of E.O. 12866 (as amended by E.O. 14094). Accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

The Department presents a detailed analysis below.

Summary of the Final Rule

This final rule modifies 42 CFR part 2 (“part 2”) to implement changes required by section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, to further align

part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules, and for clarity and consistency. Major changes are summarized in the preamble.

The Department estimates that the first-year costs for part 2 programs will total approximately \$26.1 million in 2022 dollars. These first-year costs are attributable to part 2 programs training workforce members on the revised requirements (\$13.3 million); capital expenses (\$0.9 million); compliance with breach notification requirements (\$1.6 million); updating Patient Notices (\$2.6 million); attaching consent forms for disclosures (2.9 million); updating consent forms (\$1.7 million); updating the notice to accompany disclosures (\$0.7 million); and costs to the Department for part 2 enforcement and compliance (\$2.3 million). It also includes nominal costs for responding to requests for privacy protection, providing accounting of disclosures, \$32,238 for receiving complaints, and \$61,726 for investigative agencies to file reports to the Secretary. For years 2 through 5, the estimated annual costs of

\$5.7 million are primarily attributable to compliance with attaching consent forms and breach notification requirements and related capital expenses, on top of variable Federal costs amounting to roughly \$2.3 to \$2.5 million from years 1 to 5.

The Department estimates annual cost savings of \$13.4 million per year, over 5 years, attributable to reductions in the need for part 2 programs to obtain written patient consent for disclosures for TPO (\$10.3 million), reductions in the need for covered entities and business associates to obtain written patient consent for redisclosures (\$2.6 million), and reductions in capital expenses for printing consent forms (\$0.5 million).³²²

The Department estimates net costs for part 2 programs totaling approximately \$12.7 million in the first year followed by net savings of approximately \$5.4 to \$5.2 million in years 2 to 5, resulting in overall net cost savings of approximately \$8.4 million over 5 years. The yearly costs, cost-savings and net for part 2 are displayed in Table 1 below.

Table 1. Part 2 Estimated 5-Year Costs and Cost-Savings, Undiscounted, in Millions.

Total Part 2 Costs and Cost-Savings (2022 dollars)						
Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Total, Costs	\$26.1	\$8.0	\$8.1	\$8.2	\$8.2	\$58.7
Cost-Savings	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Total, Cost-savings	\$13.4	\$13.4	\$13.4	\$13.4	\$13.4	\$67.1
Net (negative = savings)	Year 1	Year 2	Year 3	Year 4	Year 5	Total
	\$12.7	(\$5.4)	(\$5.3)	(\$5.3)	(\$5.2)	(\$8.4)

Need for the Final Rule

On March 27, 2020, Congress enacted the CARES Act as Public Law 116–136. Section 3221 of the CARES Act amended 42 U.S.C. 290dd–2, the statute that establishes requirements regarding the confidentiality and disclosure of certain records relating to SUD, and

section 3221(i) of the CARES Act requires the Secretary to promulgate regulations implementing those amendments.³²³ With this final rule, the Department changes part 2 to implement section 3221 of the CARES Act, increase clarity, and decrease compliance burdens for regulated

entities. The Department believes the changes will reduce the need for data segmentation within entities subject to the regulatory requirements promulgated under part 2.

Significant differences in the permitted uses and disclosures of part 2 records and protected health information (PHI) as defined under the

³²² Totals in this Regulatory Impact Analysis may not add up due to showing rounded numbers in the tables.

³²³ Section 3221(i) of the CARES Act requires implementation on or after the date that is 12

months after the enactment of the CARES Act, *i.e.*, March 27, 2021.

HIPAA Privacy Rule contribute to ongoing operational compliance challenges. For example, under the previous rule, entities subject to part 2 must obtain prior written consent for most uses and disclosures of part 2 records, including for TPO, while the HIPAA Privacy Rule permits many uses and disclosures of PHI without authorization. Therefore, to comply with both sets of regulations, HIPAA covered entities subject to part 2 must track and segregate part 2 records from other health records (e.g., records that are protected under the HIPAA regulations but not part 2).³²⁴

In addition, once PHI is disclosed to an entity not covered by HIPAA, it is no longer protected by the HIPAA regulations. In contrast, part 2 strictly limits redisclosures of part 2 records by individuals or entities that receive a record directly from a part 2 program or other “lawful holder” of patient identifying information, absent written patient consent.^{325 326} Therefore, any part 2 records received from a part 2 program or other lawful holder must be segregated or segmented from non-part 2 records.³²⁷ The need to segment part 2 records from other health records created data “silos” that hamper the integration of SUD treatment records into entities’ electronic record systems and billing processes, which in turn may impact the ability to integrate treatment for behavioral health conditions and other health conditions.³²⁸ Many stakeholders, including public commenters on the NPRM, have urged the Department to take action to eliminate the need for such data segmentation,³²⁹ and the

Department believes this final rule will reduce the need for data segmentation or tracking. Where segmentation may be necessary, we encourage the use of data standards adopted by ONC on behalf of HHS in 45 CFR part 170, subpart B, and referenced in the ONC Health IT Certification Program certification criteria for security labels and segmentation of sensitive health data.

Response to Public Comment

The Department requested public comment on all aspects of the proposed amendments to the regulations at 42 CFR part 2, Confidentiality of Substance Use Disorder Patient Records. Seventy-two commenters, both individuals and organizations, offered views on various aspects related to the Regulatory Impact Analysis (RIA).

Comments from organizations who expressed support for specific issues in the NPRM pointed to a decrease in the administrative burden and cost on providers, an increase in access to care, a decrease in costs for patients, and a general improvement in communication within the industry. One organization suggested that the changes in the rule will allow for streamlining care by decreasing the number of times the provider must ask for consent from the patient. Another organization asserted that the proposed rule changes could help minimize the stigma surrounding SUD treatment and help decrease the technical burdens that the previous rules have caused.

Organizations and government entities who expressed opposition to specific issues in the NPRM asserted that the changes would increase costs and legal liability for both patients and providers, decrease the quality of care, create additional administrative and technical burdens, and be overly time consuming to follow. A government organization asserted that most current electronic health care record systems do not have the ability to give accountings of TPO disclosures, which would force the entities using these systems to manually process the information. This is a burdensome and time-consuming task, according to the organization, as the entities may have to account for disclosures for the previous six years. An organization argued that due to differences in Patient Notice

requirements for part 2 and HIPAA, there may be different language for each privacy notice. Multiple organizations asserted that changing the language of the privacy notices is expensive, especially for larger organizations. One organization suggested that the expanded requirement to provide TPO accounting will lead to changes in the health care system and increased costs for patients. Another organization argued that the separation of part 2 data will lead to delays in care and threats to patient health as providers may not be able to see a patient’s full medical history, which is necessary to give adequate care. One commenter argued that the proposed change could weaken patient privacy and lead to the information being misused in criminal investigations and court proceedings. This change also may put an additional burden on providers to counsel patients on the ethical and constitutional considerations that will go into signing the form.

Organizations and government entities who expressed mixed views on the issues discussed in the excerpts change agreed with the need for the rule change and the general change itself but provided additional comments on concerns related to specific topics such as TPO disclosures and notices of privacy protections. One organization argued that HHS should take into consideration the time and costs associated with updating changes to the accounting of disclosures requirement and the timeframe to implement these changes. Another organization requested that accounting for TPO disclosures be delayed until regulations pursuant to the HITECH Act are enacted. This commenter asserted that applying the accounting requirement only to TPO disclosures made through an electronic health care record creates a disincentive to adopt electronic health care records, especially for small and rural providers and those serving patients of color and other historically underserved communities. Multiple organizations argued that if discrepancies exist between part 2 and HIPAA, there may be administrative burdens surrounding data segregation. Due to this part 2 and HIPAA need to be aligned as much as possible to minimize impediments to critical care. One organization believed that it is unnecessary for part 2 to include providing a copy of a patient’s consent and imposing retention periods on maintaining those consents since other laws, such as HIPAA, CMS regulations, and state licensing requirements already cover these requirements.

³²⁴ For example, a clinic that provides general medical services, and has a unit specializing in SUD treatment that is a part 2 program, would need to segregate its SUD records from other medical records, even for the same patient, to ensure that the SUD records are used and disclosed only as permitted by part 2.

³²⁵ See 42 CFR 2.12(d)(2)(i)(C).

³²⁶ See definition of “Patient identifying information” in 42 CFR 2.11. See also definition of “Disclose” in 42 CFR 2.11.

³²⁷ See 42 CFR 2.12(d)(2)(ii).

³²⁸ Dennis McCarty, Traci Rieckmann, Robin L. Baker, et al., “The Perceived Impact of 42 CFR part 2 on Coordination and Integration of Care: A Qualitative Analysis,” *Psychiatric Services* (Nov. 2016), <https://doi.org/10.1176/appi.ps.201600138>.

³²⁹ For example, the Ohio Behavioral Health Providers Network (Network) in an August 21, 2020, letter to SAMHSA, and the Partnership to Amend Part 2 in a similar January 8, 2021, letter to the U.S. Department of Health and Human Services (HHS), both urge that there should be no requirement for data segmentation or segregation after written consent is obtained and part 2 records are transmitted to a health information exchange or care management entity that is a business associate of a covered entity covered by the new CARES Act consent language. In the letter, the Network states that such requirements are difficult to implement in

health centers and other integrated settings in which SUD treatment may be provided. See also public comments expressed and summarized in 85 FR 42986 (July 15, 2020); and see Letter from The Partnership to Amend 42 CFR part 2 to HHS Secretary Becerra (Jan. 8, 2021), https://aahd.us/wp-content/uploads/2021/01/PartnershipRecommendationsforNextPart2-uleLtrtoNomineeBecerra_01082021.pdf.

After reviewing the comment submissions, the Department is making the following changes to this RIA, some of which result in changes to the RIA analysis presented in the proposed rule.³³⁰ Changes to the RIA also include updating wage rates and other cost factors to 2022 dollars to reflect more recent data, adding small quantitative burdens, and qualitatively discussing changes from the proposed to the final rule when unquantifiable.

- Adding a new quantitative recurring cost for receiving a complaint;
- Adding reference to the changes to the investigative agency definition;
- Adding a qualitative discussion of reasonable diligence steps for the limitation on liability for investigative agencies and their potential impacts on costs;
- Increasing the time required and the number of responses in the quantitative costs for the right to request restrictions;
- Adding a qualitative discussion of requirements for intermediaries;
- Adding a qualitative discussion of the benefit associated with the removal of data segmentation requirements;
- Adding qualitative discussion of SUD counseling notes which the Department does not expect to impose a quantifiable burden;
- Adding a new quantitative recurring cost for the requirement to attach consent with each disclosure or

provide clear description of scope of consent;

- Including a clarification that qualified service organizations (QSOs) are also subject to breach notification requirements in the quantification of these costs;
- Qualitatively discussing the impacts of part 2 programs being required to notify recipients of a revocation of consent.

Cost-Benefit Analysis

a. Overview and Methodology

This RIA relies on the same data source used by SAMHSA for the estimated number of part 2 programs in SAMHSA's 2020 Information Collection Request (ICR) ("part 2 ICR")³³¹ and uses an updated statistic from that source. The final rule also adopts the estimated number of covered entities used in the Department's 2021 ICR for the HIPAA Privacy Rule NPRM ("2021 HIPAA ICR"),³³² as well as its cost assumptions for many requirements of the HIPAA regulations, including breach notification activities.

Although HIPAA was a component of the proposed rule and is not for the final rule, the HIPAA number of covered entities (774,331) are still used in some

calculations of costs from part 2 such as for breach notifications. When applying HIPAA cost assumptions to part 2 programs, the Department multiplies the figures by 2 percent (.02), representing the number of part 2 programs in proportion to the total number of covered entities. In some instances, the estimates historically used by the Department for similar regulatory requirements were developed based on different methodologies, resulting in significantly different fiscal projections for some required activities. This RIA adopts the approach used for HIPAA's projected costs and cost savings.

In addition to the quantitative analyses of the effects of the regulatory modifications, the Department analyzes some benefits and burdens qualitatively; relatedly, there is uncertainty inherent in predicting the actions that a diverse scope of regulated entities might take in response to this final rule.

For reasons explained more fully below, the changes to the consent requirements for part 2 programs and redisclosure permissions for covered entities and business associates would result in economic cost savings of approximately \$67,107,778 over 5 years based on the final rule changes. Table 2 presents the undiscounted and discounted costs and cost savings figures over 5 years. All estimates are presented in millions of year-2022 dollars, using 2024 as the base year for discounting.

³³⁰ Specific changes to the proposed rule RIA are discussed in each of the RIA sections where applicable.

³³¹ 85 FR 42986.

³³² While the number of covered entities used in this final rule was adopted from the 2021 ICR for the HIPAA Privacy Rule, these numbers are also reflected in the more recent 2023 ICR for the HIPAA Privacy Rule NPRM and are the most up to date numbers the Department has. These ICRs may be found under OMB control # 0945-0003.

Table 2. Accounting Table.

Accounting Table of Estimated Benefits and Costs of All Final Rule Changes, in Millions, 2022 dollars						
COSTS	Year 1	Year 2	Year 3	Year 4	Year 5	Total*
Undiscounted	\$26.1	\$8.0	\$8.1	\$8.2	\$8.2	\$58.7
3% Discount	\$26.1	\$7.8	\$7.6	\$7.5	\$7.3	\$56.4
7% Discount	\$26.1	\$7.5	\$7.1	\$6.7	\$6.3	\$53.7
COST SAVINGS	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Undiscounted	\$13.4	\$13.4	\$13.4	\$13.4	\$13.4	\$67.0
3% Discount	\$13.4	\$13.0	\$12.7	\$12.3	\$11.9	\$63.3
7% Discount	\$13.4	\$12.5	\$11.7	\$11.0	\$10.2	\$58.9
NET (undiscounted)						Costs \$8.4
Non-quantified benefits and costs are described below.						

* Totals may not add up due to rounding.

b. Baseline Assumptions

In developing its estimates of the potential costs and cost savings of the final rule the Department relied substantially on recent prior estimates for modifications to this regulation³³³ and the HIPAA Privacy Rule³³⁴ and associated ICRs. Specifically, the part 2 ICR data previously approved under OMB control #0930–0092 informs the Department's estimates with respect to final rule modifications to part 2 provisions.³³⁵ However, for final rule part 2 provisions that are based on provisions of the HIPAA regulations, the Department relies on the HIPAA regulatory ICRs previously approved under OMB control # 0945–0003 and updated consistent with the 2021 HIPAA Privacy Rule NPRM.³³⁶

Because the Department lacks data to determine the percentage of part 2 programs that are also subject to the HIPAA regulations, the Department assumes for purposes of this analysis that the final rule changes to part 2 would affect all part 2 programs equally—including those programs that are also HIPAA covered entities, and

thus already are subject to requirements under the HIPAA regulations (*e.g.*, breach notification) that the Department incorporates into part 2. Thus, this RIA likely overestimates the overall compliance burden on part 2 programs posed by the final rule. In contrast, this RIA likely underestimates the cost savings of the final rule. The estimated cost savings are primarily attributed to the reduction in the number of written patient consents that would be needed to use or disclose records for TPO and to redisclose them for other purposes permitted by the HIPAA Privacy Rule. Because the Department lacks data to estimate the annual numbers of written patient consents and disclosures to covered entities, this RIA adopts an assumption that only three consents per patient are currently obtained per year (one each for treatment, payment, and health care operations) and only one half of such consents result in a disclosure of records to a HIPAA covered entity or business associate, for which consent would be no longer required to use or redisclose the record under the final rule.

c. Part 2 Programs, Covered Entities, and Patient Population

The Department relies on the same source as the approved part 2 ICR³³⁷ as the basis for its estimates of the total number of part 2 programs and total annual part 2 patient admissions. part 2 programs are publicly (Federal, State, or local) funded, assisted, or regulated SUD treatment programs. The part 2 ICR's estimate of the number of such programs (respondents) is based on the results of the 2020 National Survey of Substance Abuse Treatment Services (N–SSATS), and the average number of annual total responses is based on the results of the average number of SUD treatment admissions from SAMHSA's 2019 Treatment Episode Data Set (TEDS) as the number of patients treated annually by part 2 programs, both approved under OMB Control No. 0930–0335.³³⁸ In the 2020 data from N–SSATS, the number of part 2 respondents was 16,066.³³⁹ The TEDS data for SUD treatment admissions has been updated, so the Department relies on the 2019 statistic, as shown in Table 3 below.

³³³ See 83 FR 239 (Jan. 3, 2018) and 85 FR 42986.

³³⁴ 86 FR 6446 (Jan. 21, 2021).

³³⁵ 85 FR 42986.

³³⁶ 84 FR 51604 (Sept. 30, 2019). See also 86 FR 6446.

³³⁷ 85 FR 42986.

³³⁸ 84 FR 787 (Jan. 31, 2019).

³³⁹ See Substance Abuse and Mental Health Servs. Admin., “National Survey of Substance Abuse Treatment Services (N–SSATS): 2020. Data

on Substance Abuse Treatment Facilities” (2021), https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.

Table 3. Part 2 Programs, Covered Entities, and Patients.

Estimated Number of Part 2 Programs	Total Annual Part 2 Program Admissions
16,066	1,864,367 ³⁴⁰
Estimated Number of Covered Entities	Total Annual New Patients
774,331 ³⁴¹	613,000,000 ³⁴²

For purposes of calculating estimated costs and benefits the Department relies on mean hourly wage rates for

occupations involved in providing treatment and operating health care facilities, as noted in Table 4 below.

This final rule updates the proposed rule RIA wages to the most recent year of available data.

Occupational Pay Rates (2022 dollars)^a	
Occupation Code and Title	Hourly Wage Rate x 2^b
00-0000 All Occupations	\$59.52
43-3021 Billing and Posting Clerks	\$43.08
29-0000 Healthcare Practitioners and Technical Occupations	\$93.04
29-9021 Health Information Technologists and Medical Registrars	\$62.76
15-1212 Information Security Analysts	\$115.26
23-1011 Lawyer	\$157.48
13-1111 Management Analysts	\$100.64
11-9111 Medical and Health Services Manager	\$123.06
29-2072 Medical Records Specialist	\$49.12
43-0000 Office and Administrative Support Occupations	\$43.80
11-2030 Public Relations and Fundraising Managers	\$136.80
21-1018 Substance Abuse, Behavioral Disorder, and Mental Health Counselors	\$54.06
13-1151 Training and Development Specialist	\$67.18
43-4171 Receptionist and Information Clerk	\$33.28
15-1255 Web and Digital Interface Designer	\$97.82

a. Bureau of Labor Statistics, U.S. Department of Labor, "Occupational Employment and Wages" May 2022, https://www.bls.gov/oes/current/oes_stru.htm.

b. To incorporate employee fringe benefits and other indirect costs, these figures represent a doubling of the Bureau of Labor Statistics (BLS) mean hourly wage.

³⁴⁰ Substance Abuse and Mental Health Servs. Admin., Ctr. for Behavioral Health Statistics and Quality, "Treatment Episode Data Set (TEDS): 2019. Admissions to and Discharges From Publicly

Funded Substance Use Treatment" (2021), https://www.samhsa.gov/data/sites/default/files/reports/rpt35314/2019_TEDS_Proof.pdf.

³⁴¹ 86 FR 6446, 6497.

³⁴² *Id.* at 6515.

d. Qualitative Analysis of Non-Quantified Benefits and Burdens

The Department's analysis focuses on primary areas of changes imposed by the final rule that are likely to have an impact on regulated entities or patients. These are changes to establish or modify requirements with respect to: enforcement and penalties, notification of breaches, consent for uses and disclosures, Patient Notice, notice accompanying disclosure, copy of consent accompanying disclosure, requests for privacy protection, accounting of disclosures, audit and evaluation, disclosures for public health, and use and disclosure of records by investigative agencies. In addition to these changes, the Department believes the modifications to part 2 for clarification, readability, or consistency with HIPAA terminology, would have the unquantified benefits of providing clarity and regulatory certainty. The provisions that fall into this category and for which anticipated benefits are not discussed in-depth, are:

Sections 2.1, 2.2, 2.4, 2.11 Through 2.15, 2.17, 2.19 Through 2.21, 2.23, 2.24, 2.34, 2.35, 2.52, and 2.61 Through 2.65

The Department provides its analysis of non-quantified benefits and burdens for the primary areas of final rule regulatory change below, followed by estimates and analysis of quantified benefits and costs in section (e).

Section 2.3—Civil and Criminal Penalties for Violations

The Department creates limitations on civil and criminal liability for investigative agencies in the event they unknowingly receive part 2 records in the course of investigating or prosecuting a part 2 program or other person holding part 2 records prior to obtaining the required court order under subpart E. This safe harbor promotes public safety by permitting agencies to investigate part 2 programs and persons holding part 2 records in good faith with a reduced risk of HIPAA/HITECH Act penalties. The liability limitations would be available only to agencies that could demonstrate reasonable diligence in attempting to determine whether a provider was subject to part 2 before making a legal demand for records or placement of an undercover agent or informant. The changes benefit SUD providers, part 2 programs, investigative agencies, and the courts by encouraging agencies to seek information about a provider's part 2 status in advance and potentially reduce the number of instances where applications for good cause court orders are denied.

Incentivizing investigative agencies to check whether part 2 applies in advance of investigating a provider would benefit the court system, programs public safety, patients, and agencies by enhancing efficiencies within the legal system, promoting the rule of law, and ensuring the part 2 protections for records are utilized when applicable.

The limitations on liability for investigative agencies may result in more disclosures of patient records to such agencies by facilitating investigations and prosecutions of part 2 programs and lawful holders. The Department believes that limiting the application of § 2.3(b) to investigations and prosecutions of programs and holders of records, requiring non-identifying information in the application for the requisite court orders,³⁴³ and keeping patient identifying information under seal³⁴⁴ will provide strong and continuing protections for patient privacy while promoting public safety.

Section 2.12—Applicability

The final rule removes data segmentation requirements and instead expressly states that segregation of records is not required upon receipt. This results in the final rule neither requiring nor prohibiting data segmentation, leading to a benefit to covered entities, according to public comments on this issue. The Department acknowledges that there is likely a burden reduction from the express statement that segmentation of data or records is not required; however, the Department lacks data on the number of records benefitting from the removal of the data segmentation requirement to quantify this impact.

Section 2.16—Security for Records and Notification of Breaches

The Department adds notification of breaches to § 2.16 so that the requirements of 45 CFR 164.400 through 164.414, apply to breaches of part 2 records programs in the same manner as those requirements apply to breaches of PHI. Notification of breaches is a cornerstone element of good information practices because it permits affected individuals or patients to take steps to remediate harm, such as putting fraud alerts on their credit cards, checking their credit reports, notifying financial institutions, and informing personal contacts of potential scams involving the patient's identity. It is difficult to quantify the value of receiving notification in comparison to

the costs incurred in restoring one's credit, correcting financial records, or the cost of lost opportunities due to loss of income or reduced credit ratings.³⁴⁵

The benefit to the patient of learning about a breach of personally identifying information includes the opportunity for the patient to take timely action to regain control over their information and identity. The Department does not have data to predict how many patients will sign up for credit monitoring or other identity protections after receiving a notification of breach of their part 2 records; however, the Department believes that the costs to patients of taking these actions³⁴⁶ will be far outweighed by the savings of avoiding identity theft.³⁴⁷ Requiring part 2 programs to provide breach notification ensures that patients of such programs are provided the same awareness of breaches as patients that receive other types of health care services from HIPAA covered entities.

Section 2.22 Patient Notice

Patients, part 2 programs, and covered entities are all likely to benefit from final rule changes to more closely align the Patient Notice and HIPAA NPP regulatory requirements, which simplify their compliance with the two regulations. The Department establishes for patients the right to discuss the Patient Notice with a person designated by the program as the contact person and to include information about this right in the header of the Patient Notice as proposed in the HIPAA Coordinated Care and Individual Engagement NPRM.³⁴⁸ These changes help improve a patient's understanding of the program's privacy practices and the patient's rights with respect to their records. Even for patients who do not request a discussion under this final rule, knowledge of the right may promote trust and confidence in how their records are handled.

Section 2.24 Requirements for Intermediaries

The final rule adopts a definition of "intermediary" that excludes part 2 programs, covered entities, and business associates. Business associates that are HIEs will particularly benefit from being excluded from the definition of

³⁴⁵ See 74 FR 42739, 42765–66 (Aug. 24, 2009).

³⁴⁶ See Alexandria White, "How much does credit monitoring cost?" CNBC (Nov. 16, 2021), <https://www.cnbc.com/select/how-much-does-credit-monitoring-cost/>.

³⁴⁷ See Kenneth Terrell, "Identity Fraud Hit 42 Million People in 2021," AARP (Apr. 7, 2022) ("[T]he average per-victim loss from traditional identity fraud [is] \$1,551."), <https://www.aarp.org/money/scams-fraud/info-2022/javelin-report.html>.

³⁴⁸ See 86 FR 6446, 6485.

³⁴³ See § 2.66 (requiring use of "John Doe").

³⁴⁴ See §§ 2.66 and 2.67.

“intermediary” because HIEs were the most representative example of an intermediary; therefore, had the most to benefit from burden reduction. They will not be subject to the requirement in § 2.24 to provide a list of disclosures upon request of a patient; they will not be subject to the special consent requirements for intermediaries that many HIEs have found to be a barrier to accepting part 2 records in their systems; and they will be generally included when a patient signs a TPO consent. This will also benefit covered entities that are part 2 programs because they will be able to use an HIE business associate to exchange part 2 data as well as PHI, furthering the integration of behavioral health information with other health information. We believe this will also benefit patients because it will enhance their ability to receive comprehensive care.

Section 2.25 Accounting of Disclosures

Adding a requirement to account for disclosures for TPO through an electronic health record (EHR) benefits patients by increasing transparency about how their records are used and disclosed for those purposes. This requirement could counterbalance concerns about loss of control that patients may experience as a result of the changes to the consent process that would permit all future TPO uses and disclosures based on a single general consent. The data logs that part 2 programs need to maintain to create an accurate and complete accounting of TPO disclosures could also be beneficial for such programs in the event of an impermissible access by enabling programs to identify the responsible workforce member or other wrongful actor.

Section 2.26 Right To Request Privacy Protection for Records

Adding a new right for patients to request restrictions on uses and disclosures of their records for TPO is likely to benefit patients by giving them a new opportunity to assert their privacy interests to part 2 program staff, to address patients' concerns about who may see their records, and to understand what may be done with the information their records contain.

With respect to the right for patients to restrict disclosures to their health plan when patients have self-paid in full for services, patients will benefit by being shielded from potential harmful effects of some health plans' restrictive coverage policies or other potential negative effects, such as employers

learning of patients' SUD diagnoses.³⁴⁹ This right may also improve rates of access to SUD treatment because of patients' increased trust that they have the opportunity to ensure that their records will remain within the part 2 program. A limitation on the benefits of this right is that it is only available to patients with the means to pay privately for SUD treatment.

Part 2 programs may benefit from increased frequency of patients paying in full out of pocket, which could decrease the time spent by staff in billing and claims activities. Part 2 programs also may benefit from increased patient trust in the programs' protection of records.

Section 2.31 Consent Requirements and § 2.33 Uses and Disclosures Permitted With Written Consent

The changes to consent for part 2 records are two-fold: changes to the required elements on the written consent form and a reduction in the instances where a separate written consent is needed (the process of obtaining consent). Changes to the consent form for alignment with the HIPAA authorization form would likely benefit part 2 programs because they would employ more uniform language and concepts related to information use and disclosure. Such changes may particularly benefit part 2 programs that are also subject to the HIPAA regulations, so staff do not have to compare and interpret different terms on forms that request the use or disclosure of similar types of information.

Permitting patients to sign a single general consent for all uses and disclosures of their record for TPO, may carry both burdens and benefits to patients. Patients may benefit from a reduction in the amount of paperwork they must sign to give permission for routine purposes related to the treatment and payment and associated reductions in time spent waiting for referrals, transfer of records among providers, and payment of health insurance claims. At the same time, patients may experience a sense of loss of control over their records and the information they contain when they lose the opportunity to make specific

decisions about which uses and disclosures they would permit. In some instances, the reduced ability to make specific use and disclosure decisions could result in a greater likelihood of harm to reputation, relationships, and livelihood.

Part 2 programs would likely benefit from the efficiencies resulting from permitting a general consent for all TPO uses and disclosures by freeing staff from burdensome paperwork. In contrast, clinicians in part 2 programs may find it harder to gain the therapeutic trust needed for patients to divulge sensitive information during treatment if patients become less confident about where their information may be shared and their ability to control those uses and disclosures. Some potential patients may avoid initiating treatment altogether, which would harm both patients and programs.

Covered entities and business associates would benefit markedly from the ability to follow only one set of Federal regulations when making decisions about using and disclosing part 2 records by streamlining processes and simplifying decision making procedures. Additionally, covered entities and business associates would no longer need to segregate SUD treatment data and could improve care coordination and integration of behavioral health with general medical treatment, resulting in comprehensive holistic treatment of the entire patient.

In contrast, this final rule could also create a burden because covered entities and business associates subject to part 2 may need to sort and filter part 2 records for certain uses and disclosures, such as audit and evaluation activities that are health care operations, according to whether or not a patient consent for TPO has been obtained.

Section 2.32 Notice and Copy of Consent To Accompany Disclosure

The revisions to the notice accompanying each disclosure of part 2 records made with written consent benefit patients by ensuring that recipients of part 2 records are notified of the expanded prohibition on use of such records against patients in legal proceedings even though uses and redisclosures for other purposes would be more readily permissible. Due to the final rule changes in redisclosure permissions for recipients of part 2 records that are covered entities and business associates, the importance of the Notice to Accompany Disclosure would increase.

Part 2 programs will benefit from having notice language that accurately

³⁴⁹ Nat'l Academies of Sciences, Engineering, and Medicine, The Nat'l Acad. Press, “Ending Discrimination Against People with Mental and Substance Use Disorders: The Evidence for Stigma Change” (2016), <http://www.nap.edu/23442>; U.S. Dep't of Health and Human Servs., Office of the Surgeon General, “Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health” (Nov. 2016), <https://store.samhsa.gov/sites/default/files/d7/priv/surgeon-generals-report.pdf>.

reflects statutory changes in the privacy protections for records. Retaining the notice to accompany disclosure requirement would also ensure that certain protections for part 2 records continue to “follow the record,” compared to the HIPAA Privacy Rule whereby protections are limited to PHI held by a covered entity or business associate.

Section 2.53 Management Audits, Financial Audits, and Program Evaluation

Part 2 programs that are also covered entities would benefit from the final rule changes that would clarify that the limits on use and disclosure for audit and evaluation purposes do not apply to covered entities and business associates to the extent these activities fall within the HIPAA Privacy Rule disclosure permissions for health care operations. This benefit provides regulatory flexibility for covered entities when part 2 records are subject to audit or evaluation.

In some instances, a third-party auditor or evaluator may also be a part 2 program or a covered entity or business associate. As recipients of part 2 records, such third parties would be permitted to redisclose the records as permitted by the HIPAA Privacy Rule, with patient consent for TPO. This flexibility would not extend to government oversight audits and evaluations.

Section 2.54 Disclosures for Public Health

The Department creates a new permission to disclose de-identified records without patient consent for public health activities, consistent with statutory changes. This benefits public health by permitting records to be disclosed that would address the opioid overdose crisis and other public health issues related to SUDs, and it protects patient confidentiality because the permission is limited to disclosure of de-identified records.

Section 2.66 Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Investigate or Prosecute a Part 2 Program or the Person Holding the Records

The Department specifies the actions investigative agencies should take when they discover in good faith that they

have received part 2 records without obtaining the required court order, such as securing the records, ceasing to use or disclose the records, applying for a court order, and returning or destroying the records, as applicable to the situation. This final rule would provide the benefit of enabling agencies to move forward with investigations when they have unknowingly sought records from a part 2 program. The final rule limits the liability of investigative agencies that unknowingly obtain records without the necessary court order and increase agencies’ effectiveness in prosecuting programs. The minimal burden for exercising reasonable diligence before an unknowing receipt of part 2 records is outweighed by the reduction in risk of a penalty for noncompliance. This analysis applies as well to § 2.67 below.

Section 2.67 Orders Authorizing the Use of Undercover Agents and Informants To Investigate Employees or Agents of a Part 2 Program in Connection With a Criminal Matter

The Department’s final rule adds a requirement for investigative agencies that seek a good cause court order after placement of an undercover agent or information in a part 2 program to first meet the reasonable diligence criteria in § 2.3(b). This requirement ensures that agencies take basic actions to determine whether a SUD treatment provider is subject to part 2 before seeking to place an undercover agent or informant with the provider. As discussed above in reference to § 2.66, this final rule also has the benefit of aiding courts to streamline the application process for court orders for the use and disclosure of records.

Section 2.68 Report to the Secretary

The Department created a requirement for annual reports by investigative agencies concerning applications for court orders made after receipt of part 2 records. This new requirement benefits programs, patients, and investigative agencies by making data available about the frequency of investigative requests made “after the fact.” This requirement benefits agencies and programs by highlighting the potential need for increased awareness about part 2’s applicability. A program that makes its part 2 status

publicly known benefits from the procedural protections afforded within the court order requirements of §§ 2.66 and 2.67 in the event it becomes the target of an investigation. The final rule’s reporting requirement could also potentially serve as a deterrent to agencies from overly relying on the ability to obtain belated court orders instead of doing a reasonable amount of research to determine before making an investigative demand whether part 2 applies. Any resulting reduction in unauthorized uses and disclosures of records could be viewed as a benefit by patients and privacy advocates. In contrast, investigative agencies could view the reporting requirement as an administrative burden requiring resources that otherwise could be used to pursue investigations.

e. Estimated Quantified Cost Savings and Costs From the Final Rule

The Department has estimated quantified costs and cost savings likely to result from the final rule modifying three core expense categories (capital expenses, attaching consent forms, and workforce training) and seven substantive regulatory requirements. The remaining regulatory changes are unlikely to result in quantifiable costs or cost savings, as explained following the discussion of projected costs and savings.

i. Capital Expenses

Capital expenses related to compliance with the final rule fall into two categories: notification of breaches and printing forms and notices. The Department’s estimates for capital costs related to providing breach notification are based on estimates from the HIPAA ICR multiplied by a factor of 0.02, representing the proportion of part 2 programs compared to covered entities ($774,331 \times 16,066 = .02$). For example, for an estimated 58,482 annual breaches of PHI the Department calculates that there are 1,170 breaches of part 2 records ($58,482 \times .02 = 1,170$), and associated costs. Those costs are estimated on an ongoing annual basis because part 2 programs could experience a breach at any time that would require notification. Capital costs for breach notifications are presented in Table 5 below.

Table 5. Estimated Capital Expenses – Breach Notification.

Breach Notification Activity	# of Occurrences	Cost per Occurrence	Total Costs
Breach--Printing & Postage	1,170 ^a	\$765.04 ^b	\$894,822
Breach--Posting Substitute Notice	55 ^c	\$510.06	\$28,012
Breach--Call Center	55	\$79.10 ^d	\$4,344
TOTAL			\$927,178

a. Total number of breaches of PHI in 2015 multiplied by a factor of .02 to represent breaches of part 2 records (58,482 x .02).

b. The Department assumes that half of all affected individuals (half of 113,535,549 equals 56,767,775) would receive paper notification and half would receive notification by email. Therefore, on average, 971 individuals per breach will receive notification by mail. Further, the Department estimates that each mailed notice will cost \$.06 for paper and envelope, \$.08 for printing, and \$.60 for postage. Accordingly, on average, the capital cost for mailed notices for each breach is \$.74 for each of 971 notices, or \$719.96. The Department accepts these assumptions for part 2 breach notification costs as well.

c. The number of breaches requiring substitute notice equals all 267 large breaches and all 2,479 breaches affecting 10-499 individuals multiplied by .02 to represent breaches of part 2 records (2,746 x .02).

d. This number includes \$60 per breach for start-up and monthly costs, plus \$.35 cents per call (at a standard rate of \$.07 per minute for five minutes) for an average of 41.25 individual calls per breach and is then adjusted to 2022 dollars (from 2021 dollars).

The Department's estimate of the costs for printing revised consent forms is based on SAMHSA's part 2 ICR estimates for total annual patient admissions to part 2 programs³⁵⁰ at a rate of \$0.11 per copy. Programs are already required to print forms and notices on an ongoing basis and no change to the number of such forms and notices is projected, so the Department has not added any new capital costs for printing the revised Patient Notice and Notice to Accompany Disclosures. However, the Department estimates that as a result of changes to the requirement to obtain consent for disclosures related to TPO, part 2 programs and covered entities and business associates would experience cost savings from a significant reduction in the number of needed consent forms. The Department assumes that, on average, each patient's treatment results in a minimum of three written consents obtained by part 2

programs, one each for treatment, payment, and health care operations purposes. The final rule is estimated to result in a decrease in the total number of consents by two-thirds because only one patient consent would be required to cover all TPO uses and disclosures. At an estimated cost of \$0.11 per consent, for a total of 1,864,367 annual patient admissions, this would result in an annual cost savings to part 2 programs of 3,728,734 fewer written consents, or \$396,222.

Additionally, covered entities and business associates that receive part 2 records will also experience a reduced need to obtain written patient consent or a HIPAA authorization because redisclosure under the HIPAA Privacy Rule does not require patient consent or authorization for TPO and many other purposes. The Department lacks data to make a precise estimate of projected cost savings, but each patient record

disclosed to a covered entity or business associate would potentially generate a savings based on eliminating the need for the recipient to obtain additional consent for redisclosure. The Department has adopted a low-cost savings estimate that one-half of part 2 annual admissions would result in receipt of part 2 records by a covered entity or business associate that would no longer be required to obtain specific written patient consent to redisclose such record, representing an annual capital expense savings from printing 932,184 fewer consent forms. At a per-consent cost of \$0.11,³⁵¹ this would result in annual savings of \$99,056. The capital expense savings for printing consent forms are presented in Table 6 below. The savings related to the cost of staff time to obtain the patient consent are estimated and discussed separately in the section on consent below.

³⁵⁰ Substance Use Disorder Patient Records Supporting Statement A_06102020—OMB 0930-0092, <https://omb.report/omb/0930-0092>.

³⁵¹ The Department relies on its estimated capital expenses for printing HIPAA breach notification letters adjusted to 2022 dollars. See 2021 HIPAA

ICR, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-0945-001.

Table 6. Estimated Capital Expense Savings - Printing Consent Forms.

Regulatory Activity	# of Occurrences	Cost per Occurrence	Total Cost Savings
Reduction in Consent Forms for Part 2 Programs	3,728,734	\$0.11	\$396,222
Reduction in Consent Forms for CEs & BAs	932,184	\$0.11	\$99,056
TOTAL ANNUAL SAVINGS			\$495,278

ii. Training Costs

Although part 2 does not expressly require training and the final rule does not require retraining, the Department anticipates that all part 2 programs will choose to train their workforce members on the modified part 2 requirements to ensure compliance. The Department estimates costs that all part 2 programs would incur to train staff on the changes to the confidentiality requirements. As indicated in the chart below, only certain staff would need to be trained on specific topics and each program would rely on a training specialist whose preparation time would also be

accounted for. Compared to the proposed HIPAA Privacy Rule right to discuss privacy practices, the costs for training part 2 counselors include a higher number of staff per program because part 2 programs have no required Privacy Officer who is already assigned similar duties and are more likely to incur costs for developing a new training regimen. The Department of Labor, BLS last reported statistics for substance use and behavioral disorder counselors separate from mental health counselors in 2016, and substance use and behavioral disorder counselors represented 65 percent of the combined

total. The Department thus calculates its estimate for the number of substance use and behavioral disorder counselors as 65 percent of the workers in the BLS occupational category for “substance abuse, behavioral disorder, and mental health counselors” and uses that as a proxy for the number of part 2 program counselors that would require training on the new Patient Notice.³⁵² The Department estimates that a total of \$13.3 million in one-time new training costs would be incurred in the first year of the final rule’s implementation, as presented in Table 7 below.

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³⁵² This final rule RIA updates the number of counselors based on more recent data from the May 2022 National Occupational Employment and Wage

Estimates. In 2022, the number of part 2 counselors is estimated to be 224,231 (344,970 substance abuse and behavioral disorder counselors separate from

mental health counselors, SOC code 21-1018) × .65).

Table 7. Estimated Workforce Training Costs.

Training Topics – Staff Member	Number of Trainees	Time in Training	Total Training Hours	Hourly Wage Rate	Total Costs
Complaint Procedures & Nonretaliation – Manager	16,066	0.75	12,050	\$123.06	\$1,482,811
Breach Notification - Manager	16,066	1	16,066	\$123.06	\$1,977,082
Obtaining Consent – Receptionist	32,132	0.5	16,066	\$33.28	\$534,676
Patient Notices & Right to Discuss – SUD Counselor	224,231 ^a	0.25	56,058	\$54.06	\$3,030,475
Requests for Restrictions - Receptionist, Medical Records, Billing Clerk	48,198	0.25	12,050	\$41.83	\$503,990
Accounting of Disclosures - Med. Records Specialist	16,066	0.5	8,033	\$49.12	\$394,581
Training Specialist's Time	16,066	5	80,330	\$67.18	\$5,396,569
TOTAL TRAINING COSTS			200,652		\$13,320,186

a. This figure is the number of SUD and behavioral disorder counselors as a proxy for the number of part 2 program counselors.

iii. Receiving a Complaint

The Department estimates a new burden in this final rule, for covered entities to receive complaints filed by patients against a program, covered entity, business associate, qualified service organization, or other lawful holder in violation of this part would

amount to a total annual labor cost of \$38,328. This estimate is derived under the assumption that one in every thousand patients would file a complaint, leading to 1,864 complaints annually.³⁵³ The complaint is also

³⁵³ The assumption that one out of every 1,000 patients would file a complaint was adopted from

assumed to be received by a manager and take 10 minutes to address. The cost of receiving complaints poses both a recurring annual cost as well as a one-time cost to establish procedures for handling complaints. It is assumed that

the 2000 HIPAA Final Rule RIA's calculation of costs of internal complaints under 45 CFR part 160.

the cost for setting up complaint procedures is captured under the training requirement as well as the

Patient Notice requirements, laid out in Tables 7 and 10 respectively. Table 8

presents the costs for receiving a complaint.

Table 8. Estimated Costs for Receiving a Complaint.

Regulatory Action	Number of Respondents	Number of Responses per Respondent	Average burden hours per Response	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Respondent Costs
2.4 Receiving a Complaint	1,864 ^a	1	0.167	322	\$123.06	\$38,238

a. It is assumed that there will be one complaint for every 1,000 patients (or part 2 Program Admissions) thus there are an estimated 1,864 respondents (1,864,367/1,000).

iv. Notification of Breaches

The Department estimates annual labor costs of \$1.6 million to part 2 programs for providing notification of breaches of unsecured records, including notification to the Secretary,

affected patients, and the media, consistent with the requirements of the HIPAA Breach Notification Rule. This estimate is derived from calculating two percent of the total estimated breach notification activities for covered entities, business associates, and

qualified service organizations under the HIPAA Breach Notification Rule.³⁵⁴ Costs for the labor spent to provide breach notifications are estimated in Table 9 below. Capital costs for providing breach notification are discussed separately in Table 5 above.

³⁵⁴ See 2021 HIPAA ICR, <https://omb.report/icr/202011-0945-001>. Wage rates are updated to 2022 figures.

Table 9. Estimated Costs of Breach Notification.

Section of 45 CFR	Notification Activity	Number of Respondents	Total Respondent Costs
164.404	Individual Notice—Written and E-mail Notice (drafting)	1,170 ^a	\$54,412
164.404	Individual Notice—Written and E-mail Notice (preparing and documenting notification)	1,170	\$25,615
164.404	Individual Notice—Written and E-mail Notice (processing and sending)	1,170	\$795,503
164.404	Individual Notice—Substitute Notice (posting or publishing)	55 ^b	\$5,372
164.404	Individual Notice—Substitute Notice (staffing toll-free number)	55	\$8,227
164.404	Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information)	2,265 ^c	\$16,854
164.406	Media Notice	5.34 ^d	\$543
164.408	Notice to Secretary (notice for breaches affecting 500 or more individuals)	5.34	\$543
164.408	Notice to Secretary (notice for breaches affecting fewer than 500 individuals)	1,164 ^e	\$50,996
164.414	500 or More Affected Individuals (investigating and documenting breach)	5.34	\$32,857
164.414	Less than 500 Affected Individuals (investigating and documenting breach) -- affecting 10-499	50	\$48,811
164.414	Less than 500 Affected Individuals (investigating and documenting breach) -- affecting <10	1,115 ^f	\$548,710
TOTAL			\$1,588,441

a. Total number of breach reports submitted to OCR in 2015 (58,482) multiplied by .02 to represent part 2 breaches.

b. All 267 large breaches and all 2,479 breaches affecting 10-499 individuals (2,746) multiplied by .02.

c. As noted in the previous footnote, this number equals 1% of the affected individuals who require substitute notification ($0.01 \times 11,326,441 = 113,264$) multiplied by .02 to represent part 2 program breaches.

d. The total number of breaches affecting 500 or more individuals in 2015, multiplied by .02 to represent the number of part 2 breaches.

e. The total number of HIPAA breaches affecting fewer than 500 individuals in 2015, multiplied by .02 to represent the number of part 2 breaches.

f. 55,736 multiplied by .02.

v. Patient Notice

The Department estimates a first-year total of \$2.6 million in costs to part 2 programs for updating the Patient Notice, as applicable, and providing patients a right to discuss the program's Patient Notice. Under the final rule's modifications to § 2.22, as under the existing rules, a part 2 program that is also a covered entity only needs to have one notice that meets the requirements of both rules, so the Department's estimates are based on an unduplicated count of part 2 programs, each one needing to update its Patient Notice. The Department's estimate is based on the number of total entities and one hour of a lawyer's time to update the notice(s), as detailed in Table 10. There

would be no new costs for providers associated with distribution of the revised notice other than posting it on the entity's website (where available), as providers have an ongoing obligation to provide the notice to first-time patients. The Department bases the estimate on its previous estimates from the 2013 Omnibus Final Rule, in which the Department estimated approximately 613 million first time visits with health care providers annually.³⁵⁵

In addition to the costs of updating the Patient Notice, the Department estimates that part 2 programs incur ongoing costs to implement the right to discuss a program's Patient Notice calculated as 1 percent of all patients, or 18,644 requests, at the hourly wage of a

substance abuse, behavioral disorder, and mental health counselor, as defined by BLS, for an average of 7 minutes per request or \$117,586 total per year. The number of discussions is based on the same percentage of new patients as the parallel proposal in the HIPAA Coordinated Care and Individual Engagement NPRM, which reflects the anticipated number of patients who would ask to speak with the identified contact person or office about the Patient Notice. It does not include the discussion that each counselor may have with a new patient about confidentiality in the clinical context which the Department views as part of treatment. Total costs for the Patient Notice are presented in Table 10 below.

Table 10. Estimated Costs for Patient Notice.

Regulatory Activity	Total Responses	Hours per response	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Annual Cost
2.22 Update Patient Notice (lawyer)	16,066	1	16,066	\$157.48	\$2,530,074
2.22 Discuss Patient Notice	18,644 ^a	0.12	2,175	\$54.06	\$117,586
TOTAL					\$2,647,659

a. Respondents are 1% of all new patients and the cost is based on the hourly wage for a substance abuse, behavioral, and mental health counselor.

vi. Accounting of Disclosures

The Department's estimate of minimal annual costs to part 2 programs for providing patients an accounting of disclosures is based on the Department's estimates for covered entities to comply with the requirements in 45 CFR 164.528 multiplied by a factor of .02. This represents two percent of the total estimated requests for an accounting of disclosures under the HIPAA Privacy Rule. The Department included this estimate in its calculations (detailed in Table 11), although it is negligible, due to the CARES Act mandate to include the requirement in part 2. In addition, these costs will not constitute an immediate burden since they are contingent on the promulgation of

HITECH Act modifications to the accounting of disclosures standard in the HIPAA Privacy Rule at 45 CFR 164.528, which the Department has not yet finalized.

The responses to the Department's 2018 Request for Information on Modifying HIPAA Rules to Improve Coordinated Care ³⁵⁶ indicated that covered entities and their business associates receive very few requests for an accounting of disclosures annually (a high of .00006).³⁵⁷ Comments received on the part 2 NPRM were consistent with these and suggested that covered entities still receive very few requests; however, one commenter asserted that a request can take approximately 40 hours of labor to address.³⁵⁸ We believe this

figure is an outlier and that most requests cover a narrow time period related to a specific disclosure concern. The Department is unable to estimate the additional burdens, if any, of offering these accountings in a machine readable or other electronic format. Further, the Department lacks specific information about the costs to revise EHR systems to generate a report of disclosures for TPO, other than they could be substantial.³⁵⁹ We note too that the compliance date for the accounting of disclosures requirement is tolled until modifications to the accounting requirement are finalized in 45 CFR 164.528 of the HIPAA Privacy Rule. Table 11 presents the estimated costs for accounting of disclosures.

³⁵⁵ 78 FR 5565, 5675 (Jan. 25, 2013).

³⁵⁶ 83 FR 64302 (Dec. 14, 2018).

³⁵⁷ See generally, public comments posted in response to Docket ID# HHS-OCR-2018-0028,

<https://www.regulations.gov/document/HHS-OCR-2018-0028-0001/comment>.

³⁵⁸ See public comments posted in response to Docket ID# HHS-OCR-2022-0018-0001, <https://www.regulations.gov/document/HHS-OCR-2022-0018-0001>.

www.regulations.gov/document/HHS-OCR-2022-0018-0001.

³⁵⁹ *Id.*

Table 11. Estimated Costs for Accounting of Disclosures.

Regulatory Action	Number of Respondents	Number of Responses per Respondent	Average burden hours per Response	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Respondent Costs
2.25 Accounting of Part 2 TPO Disclosures	100 ^a	1	0.05	5	\$49.12	\$246

a. Calculated as 2% multiplied by the estimate that covered entities annually fulfill 5,000 requests from individuals for an accounting of TPO disclosures at the hourly wage for a medical records specialist.

vii. Requests for Privacy Protection for Records

The Department estimates that part 2 programs would incur a total of \$5,019 in annual costs arising from the right to request restrictions on disclosures. OCR's HIPAA ICR estimate of costs for covered entities to comply with the parallel requirement under 45 CFR 164.522 represents a doubling of previous estimated responses from 20,000 to 40,000.³⁶⁰ However, costs remain low for compliance with this regulatory requirement, in part because the requirement to accept a patient's request for restrictions is mandatory only for services for which the patient has paid in full; the cost of complying with a request not to disclose records or PHI to a patient's health plan occurs in a context in which providers are saved

the labor that would be needed to submit claims to health insurers.

The Department acknowledges that in addition to the handling of restriction requests, providers will likely also incur costs related to the adjustment of their technological capabilities. Comments received on the part 2 NPRM outlined some of the existing shortcomings and potential improvements to the EHR systems. Some of the issues discussed included perceptions regarding the inability of current EHR systems to automatically flag and separate part 2 records, and challenges of granular data segmentation functionality, inability of systems to handle multiple types of information workflows, and difficulties in ensuring that the current systems protect part 2 data adequately from access and redistribution in large patient settings where data is received and redistributed electronically.

Commenters suggested, among others, the development of broader interoperability frameworks, and the development of consistent standards as potential remedies for those technical issues, but there was no specific actionable data provided that could inform the cost analysis of such efforts. The Department therefore lacks a basis to formally quantify these costs and does include them in this RIA.

The estimated costs for requests for privacy protection for records is presented in Table 12 below. The estimated number of responses is increased from the proposed rule to 1,200 and the average burden doubled to 6 minutes (0.1 hours) to account for the final rule adding the requirement that covered entities use reasonable effort to accommodate patient's request for restrictions resulting in a slight increase in estimated burden.

Table 12. Estimated Costs for Request for Privacy Protection for Records.

Regulatory Activity	Number of Responses [1]	Average burden hours per Response	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Respondent Costs
2.26 Requests for privacy protection	1,200	0.1	120	\$41.83	\$5,019

viii. Updated Consent Form

The Department estimates that each part 2 program would incur the costs for

40 minutes of a lawyer's time to update its patient consent form for use and disclosure of records. This would result in an estimated total nonrecurring cost

of approximately \$1.7 million, to be incurred in the first year after publication of a final rule, as detailed in Table 13 below.

³⁶⁰ 86 FR 6446, 6498. See also 84 FR 51604.

Table 13. Estimated Cost for Updating Consent Forms.

Regulatory Activity	Total Responses	Average Burden Hour	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total One-time Cost
2.31 Consent Form - Updating	16,066	0.67	10,710.67	\$157.48	\$1,686,716

ix. Attaching Consent Form

The Department estimates a new cost in this final rule (compared to the proposed rule RIA) for the requirement associated with § 2.32 that each part 2 program would need to attach consent forms with each disclosure. The

Department assumes an average of three (3) annual disclosures per patient. The Department assumes consent forms would need to be attached to paper disclosures as well as electronic disclosures and assumes ninety percent (90%) of disclosures are received

electronically while the remaining ten percent (10%) would be received in paper format. This would result in a total recurring cost of \$2.9 million per year. The estimated costs for attaching consent form are presented in Table 14 below.

Table 14. Estimated Costs for Attaching Consent Form.

Regulatory Activity	Total Responses	Average Burden Hour	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Recurring Cost (2022 dollars)
2.32 Consent Form – Attach consent form with each disclosure (Paper records disclosed)	559,310 ^a	0.08	46,609	\$33.28	\$1,551,153
2.32 Consent Form – Attach consent form with each disclosure (electronic records disclosed)	5,033,791 ^b	0.01	41,948	\$33.28	\$1,396,038
TOTAL					\$2,947,191

a. Calculated as the number of patient admissions multiplied by the number of paper consent forms that need to be attached (10% of total) times the number of disclosures per patient (3).

b. Calculated as the number of patient admissions multiplied by the number of electronic consent forms that need to be attached (90% of total) times the number of disclosures per patient (3).

x. Updated Notice To Accompany Disclosures

The Department estimates that each part 2 program would incur the costs for 20 minutes of a health care managers' time to update the regulatory notice that

is to accompany each disclosure of records with written patient consent. The Department believes that in most cases a manager can accomplish this task, rather than a lawyer, because specific text for the Notice to Accompany Disclosure is required and

is included in the final rule. For a total of 16,066 programs this would result in estimated total nonrecurring costs in the first year of the rule's implementation of approximately \$0.7 million as detailed in Table 15 below.

Table 15. Estimated Cost for Updated Notices to Accompany Disclosures.

Regulatory Activity	Time (hours)	Hourly Wage Rate w/ Benefits (Base*2)	No. of occurrences	Total Burden Hours	Total One-time Cost (2022 dollars)
2.32 Notice and Copy of Consent to Accompany Disclosure - Updating	0.33	\$123.06	16,066	5,355	\$659,027

xi. New Reporting to the Secretary

The final rule's reporting requirements in § 2.68 are directed to those agencies that investigate and prosecute programs and holders of part 2 records. Part 2 programs are subject, for example, to investigations for Medicare and Medicaid fraud and diversion of opioids used in medications for opioid use disorder (MOUD). Medicaid and Medicare fraud investigations may involve several agencies, such as the Department of Justice (DOJ), HHS Office of the Inspector General (OIG), and state agencies. Investigations involving the use and disclosure of part 2 records include those where SUD providers are the targeted entities as well as where other health care providers are the target and have received records from a part 2 program. The Department has revised its estimates of the number of investigations that involve part 2 records, resulting in an increase of more than 100 percent from the 225 estimated investigations in the NPRM. The Department estimates that approximately 506 investigations, prosecutions, or sanctions involve part 2 programs or records annually, based on FY 2021 statistics. The reported data does not separately track part 2 programs so we based our estimate on the proportion of part 2 programs as compared to covered entities, which is 2 percent, as we have done for other estimates within the analysis for this rule.³⁶¹ We acknowledge that this may not capture all the entities subject to

investigations that include part 2 records. At the same time, we have added a more extensive list of investigations and actions against health care entities, many of which represent duplicate actions, such as the removal of entities from Medicare participation based on a fraud conviction against the same entity that is also counted within the same year and counting both new fraud investigations and pending cases at the year's end. We included data from FY 2021³⁶² for the following actions:

- 831 new criminal health care fraud investigations (DOJ).
- 462 cases of criminal charges filed by Federal prosecutors.
- 805 new civil health care fraud investigations (DOJ).
- 1,432 civil health care fraud matters pending at the end of the fiscal year (DOJ).
- 107 health care fraud criminal enterprises dismantled (FBI).
- 504 criminal actions for Medicare and Medicaid crimes (HHS–OIG).
- 669 civil actions (HHS–OIG).
- 1,689 individuals and entities excluded from participation in Medicare, Medicaid, and other Federal health care programs (HHS–OIG).
- 18,815 open investigations by state Medicaid Fraud Control Units in FY 2021.³⁶³

This results in a count of 25,314 actions taken by investigative agencies and 506 as the estimated proportion involving use and disclosure of part 2 records. The Department assumes, as an over-estimate, that all 506 cases involve

use of the safe harbor under § 2.3 and result in a required report under § 2.68.

The burden on investigative agencies for annual reporting about unknowing receipt of part 2 records prior to a court order includes the labor of gathering data and submitting it to the Secretary. As a proxy for this burden, the Department estimates that the labor would be equal to reporting large breaches of PHI under HIPAA which has been calculated at 1.5 hours per response at an hourly wage rate of \$81.28³⁶⁴ for a total estimated cost of \$121.92 per response. For an estimated 506 annual investigations this would result in a total cost of \$61,726. This figure represents an overestimate because it assumes 100 percent of investigations would involve unknowing receipt of part 2 records prior to seeking a court order. The Department assumes that the actual proportion of investigations falling within the reporting requirement would be less than 25 percent of cases, although it lacks data to substantiate this assumption. The final rule also adds to the definition of investigative agencies to include local, territorial, and Tribal agencies. The Department acknowledges the potential for expanding the definition to increase the affected population for investigative agencies; however, the Department lacks sufficient data to quantify the number of additional agencies impacted by the rule. The estimated costs for new reporting to the Secretary are presented in Table 16 below.

³⁶¹ 16,066 part 2 programs/774,331 covered entities = .02

³⁶² Annual Report of the Departments of Health and Human Services and Justice, FY 2021 Health Care Fraud and Abuse Control Report (July 2022). We include data reflecting OIG investigations as one representative data point in an effort to estimate

the volume of relevant records obtained through investigations throughout the country. Annual reporting will be conducted consistent with applicable Federal laws.

³⁶³ https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/expenditures_statistics/fy2021-statistical-chart.pdf. <https://oig.hhs.gov/fraud/>

[medicaid-fraud-control-units-mfcu/expenditures_statistics/fy2021-statistical-chart.pdf](https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/expenditures_statistics/fy2021-statistical-chart.pdf).

³⁶⁴ This is a composite wage rate used in burden estimates for the Department's breach notification Information Collection Request.

Table 16. Estimated Cost for New Reporting to the Secretary.

Regulatory Activity	Total Responses	Average Burden Hour	Total Burden Hours	Hourly Wage Rate w/ Benefits (Base*2)	Total Recurring Cost (2022 dollars)
2.68 Report to Secretary	506	1.5	759	\$81.28	\$61,726

f. Summary of First Year Costs

Table 17 presents the total first year part 2 quantified costs presented in the above sections, totaling \$23.9 million.

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Table 17. Estimated Annual Part 2 Costs in First Year of Implementation.

Regulatory Activity	Total Responses	Hours per response	Total Burden Hours	Hourly Wage Rate	Total Cost
2.4 Receiving a Complaint	1,864	0.167	331	\$123.06	\$38,238
2.16 Breach Notification (from Table 9)					\$1,588,441
2.22 Updating Patient Notice	16,066	1	16,066	\$157.48	\$2,530,074
2.22 Right to Discuss	18,644	0.12	2,175	\$54.06	\$117,586
2.25 Accounting of Disclosures	100	0.05	5	\$49.12	\$246
2.26 Requests for privacy protection	1,200	0.1	120	\$41.83	\$5,019
2.31 –Updating Consent Form	16,066	0.67	10,711	\$157.48	\$1,686,716
2.32 Notice and Copy of Consent to Accompany Disclosures	16,066	0.33	5,355	\$123.06	\$659,027
2.32 Attaching Consent Form	5,593,101	0.09	88,557	\$33.28	\$2,947,191
2.68 Report to the Secretary	506	1.5	759	\$81.28	\$61,726
Workforce Training (from Table 7)					\$13,320,186
Capital Expenses (from Table 5)					\$927,178
TOTAL ANNUAL COSTS (first year)					\$23,881,628

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g. Final Rule Changes Resulting in Negligible Fiscal Impact

Sections 2.1 and 2.2 Statutory Authority and Enforcement

While civil enforcement of part 2 by the Department may increase costs for part 2 programs or lawful holders that experience a breach or become the subject of a part 2 complaint or compliance review, the costs of responding to a potential violation are not calculated separately from the costs of complying with new or changed

regulatory requirements. Thus, the Department's analysis does not estimate any program costs for the changes to §§ 2.1 and 2.2 of 42 CFR part 2.

Section 2.3 Civil and Criminal Penalties for Violations

The final rule adds local, territorial, and Tribal agencies to the investigative agency definition. In § 2.3(b)(1), investigative agencies that do not use reasonable diligence would be precluded from seeking a court order to use or disclose part 2 records that they later discover in their possession. The

Department acknowledges there may be an overall increase in the affected population associated with including local, territorial, and Tribal agencies to investigative agency definition; however, the Department lacks sufficient data on the extent these agencies are involved in investigating part 2 programs to quantify these potential impacts.

Section 2.3 also creates a limitation on civil or criminal liability for persons acting on behalf of investigative agencies when they may unknowingly receive part 2 records without first

obtaining the requisite court order. The final rule mandates reasonable diligence steps that mean taking all of the following actions:

Searching for the practice or provider among the SUD treatment facilities in SAMHSA's online treatment locator; searching in a similar state database of treatment facilities where available; checking a practice or program's website, where available, or physical location; viewing the entity's Patient Notice or HIPAA NPP if it is available; and taking all these steps within no more than 60 days before requesting records or placing an undercover agent or informant. The regulatory change encourages investigative agencies to take preventative measures, reducing the need for after-the-fact court orders. The Department acknowledges that the reasonable diligence steps may result in additional burdens for investigative agencies to check websites and visit physical locations; however, the Department lacks sufficient data to quantify the additional burden and expects that it is negligible.

Section 2.11 Definitions

Changes to the regulatory definitions are not likely to create significant increases or decreases in burdens for part 2 programs or covered entities and business associates. These entities, collectively, would benefit from the regulatory certainty resulting from clarification of terms; however, the definitions are generally intended to codify current usage and understanding of the defined terms. One change that has the potential to result in additional burden to part 2 programs but potentially represents a benefit of increased privacy protection for patients would be the inclusion of a new definition of "SUD counseling notes." The Department has discussed the potential impact to the inclusion of SUD counseling notes in § 2.31. The Department also changes the definition of "investigative agency" to include local, territorial, and Tribal agencies. This change in the definition has the potential to increase the population of investigative agencies. Additional discussion on the potential impact of adding local, territorial, and Tribal agencies is discussed in § 2.3. The final rule adds a new definition on "lawful holder" used in several provisions. The final rule also adds a new definition of "personal representative," replacing language in § 2.15 describing individuals authorized to act on a patient's behalf, as mentioned under the discussion on § 2.15 below. Another change to the definition of "intermediary" excludes part 2

programs, covered entities, and business associates and may result in burden decreases to these entities, as mentioned under the discussion on § 2.24 below. The Department estimates that these three changes will have a negligible impact.

Section 2.12 Applicability

The final rule change from "Armed Forces" to "Uniformed Services" in paragraphs (b)(1) and (c)(2) of § 2.12 is likely to result in only a negligible change in burden because this terminology is already in use in 42 U.S.C. 290dd–2. Adding "uses" and "disclosures" in several places provides clarity and consistency, but is unlikely to create quantifiable costs or cost savings. Adding the four express statutory restrictions on use and disclosure of records for court proceedings³⁶⁵ in paragraph (d)(1) of this section will likely result in no significant burden change, as the restrictions on use and disclosure of records for criminal investigations and prosecutions of patients are already stringent and the ability to obtain a court order remains. Excluding covered entities from the restrictions applied to other "third-party payers" in paragraph (d)(2) of this section would reduce burden on covered entities that are health plans because they will be permitted to disclose records for a wider range of health care operations than under the current regulation. However, this burden reduction is similar to that for all covered entities under the final rule, so the Department has not estimated the costs or benefits separately from the effects of § 2.33 (Uses and disclosures permitted with written consent).

Section 2.13 Confidentiality Restrictions and Safeguards

The primary change to this section is to remove paragraph (d) and redesignate it as § 2.24. Additionally, adding the term "use" to the circumstances when disclosures are permitted or prohibited provides clarification, but is unlikely to generate a change in burden associated with this provision.

Section 2.14 Minor Patients

The final rule changes to this section would clarify that a part 2 program director may clinically evaluate whether a minor has decision making capacity, but not issue a legal judgment to that effect. The changes also add "uses" to "disclosures" as the types of activities regulated under this section. None of

the changes would be likely to result in quantifiable burdens to part 2 programs.

Section 2.15 Patients Who Lack Capacity and Deceased Patients

The final rule replaces the terms for "guardian or other individual authorized under state law to act on the patient's behalf" with the term "personal representative" under § 2.11, as described above. The Department does not anticipate this to result in any significant burdens or benefits. The Department's final rule will also replace outdated references to incompetence and instead refer to a lack of capacity to make health care decisions and will add "uses" to "disclosures" to describe the activities permitted when certain conditions are met. These clarifications and additions are unlikely to generate a change in burden that can be quantified, and thus they are not included in the Department's calculation of estimated costs and cost savings.

Section 2.17 Undercover Agents or Informants

The final rule adds the phrase "and disclosure" in the heading of paragraph (b) of this section and "or disclosed" after "used" in paragraph (b) for consistency with changes throughout the rule to align with HIPAA language. We do not expect any change in burden as a result of this change.

Section 2.20 Relationship to State Laws

The final rule adds the term "use" to describe activities regulated by this section. Similar to 42 CFR part 2, state laws impose restrictions on uses and disclosures related to SUD and the Department assumes programs subject to regulation by this part would be able to comply with part 2 and the state law. The Department does not anticipate these changes would result in a quantifiable increase or decrease in burden.

Section 2.21 Relationship to Federal Statutes Protecting Research Subjects Against Compulsory Disclosure of Their Identity

The Department replaced "disclosure and use" with "use and disclosure" to align the language of this section with the HIPAA Privacy Rule. The edit does not require any changes to existing part 2 requirements. The Department does not anticipate this change would result in a quantifiable increase or decrease in burden.

³⁶⁵ See 42 U.S.C. 290dd–2(c).

Section 2.24 Requirements for Intermediaries

The final rule changes the definition of “intermediary” to exclude part 2 programs, covered entities, and business associates, as noted above. The Department acknowledges that this poses a burden reduction to covered entities and business associates as they are no longer subject to these requirements; however, the Department does not anticipate these changes to have a significant impact.

Section 2.31 Consent Requirements

The final rule adds a new consent requirement at § 2.31(b), requiring separate consent for the use and disclosure of SUD counseling notes. The final rule limits use and disclosure of SUD counseling notes without patient consent in a manner that aligns with the HIPAA Privacy Rule authorization requirements for psychotherapy notes. The Department believes there is a qualitative benefit to patients and clinicians who keep separate SUD counseling notes. Requiring a separate consent for SUD counseling notes offers a means for patients to selectively disclose sensitive information and reduces barriers to clinicians recording treatment information for patients concerned about their confidentiality being protected. The Department acknowledges that there is a potential increase in the administrative burden to part 2 programs for segmenting SUD counseling notes as well as obtaining an additional patient consent; however, a separate consent requirement strikes a balance between heightened protection and an appropriately tailored permission for uses and disclosures that are low risk for abuse or related to requirements in law. The Department lacks sufficient data on the number of SUD counseling notes requiring additional consent and does not expect there to be a large number; and therefore, does not anticipate these changes would result in a quantifiable increase or decrease in burden.

Section 2.34 Uses and Disclosures To Prevent Multiple Enrollments

The final rule adds the term “uses” to the heading and incorporate minor word changes and style edits for clarity. The edits do not require any changes to existing part 2 requirements. The Department does not anticipate these changes would result in a quantifiable increase or decrease in burden.

Section 2.35 Disclosures to Elements of the Criminal Justice System Which Have Referred Patients

The final rule replaces the term “individuals” with “persons,” clarify that permitted redisclosures of information are from part 2 records, and make minor word and style edits for clarity. The edits do not require any changes to existing part 2 requirements. The Department does not anticipate these changes would result in a quantifiable increase or decrease in burden.

Section 2.52 Scientific Research

The Department considered whether the requirement to align the de-identification standard in § 2.52 (and throughout part 2) with the HIPAA Privacy Rule de-identification standard in 45 CFR 164.514 would significantly increase burden for part 2 programs or result in any unintended negative consequences. The Department concluded that the final rule change would not significantly increase burden because a part 2 program would need to follow detailed protocols to ensure that the current standard is met that are similar to the level of work needed to adhere to the HIPAA Privacy Rule standard. Additionally, the final rule ensures that all part 2 programs are following similar standards for de-identification, which would benefit researchers when creating data sets from different part 2 programs, by enabling them to populate the data sets with similar content elements.

Section 2.53 Management Audits, Financial Audits, and Program Evaluation

The final rule clarifies that some audit and evaluation activities may be considered health care operations could be used by part 2 programs, covered entities, and business associates to obtain records based on consent for health care operations and then such entities could redisclose them as permitted by the HIPAA Privacy Rule. The HIPAA Privacy Rule may allow these entities greater flexibility to use or redisclose the part 2 records for permitted purposes compared to the limitations contained in § 2.53 of part 2. For part 2 programs that are covered entities, this change could result in burden reduction because they would not have to track the records used for audit and evaluation purposes as closely; however, the Department is without data to quantify the potential cost reduction. For business associates, there would likely be no change in burden because they are already

obligated by contract to only use or disclose PHI (which may be part 2 records) as allowed by the agreement with the covered entity.

As discussed in preamble, the disclosure permission under § 2.53 would continue to apply to audits and evaluations conducted by a health oversight agency without patient consent. The Department does not believe that the text of section 3221(e) of the CARES Act indicates congressional intent to alter the established oversight mechanisms for part 2 programs, including those that provide services reimbursed by Medicare, Medicaid, and Children’s Health Insurance Program (CHIP). The Department also intends that a government agency conducting activities that could fall within either § 2.53 or § 2.33 for health care operations would have the flexibility to choose which permission to rely on and would not have to meet the conditions of both sections. In the event that the agency is a covered entity that has received the records based on a consent for TPO, it could further redisclose the records as permitted by the HIPAA Privacy Rule. Further, the Department intends that the availability of the safe harbor under § 2.3 does not affect the ability of government agencies conducting health oversight to continue relying on § 2.53 to access records without a court order.

Section 2.54 Disclosures for Public Health

The Department does not believe that an express permission to disclose records to public health authorities without patient consent will impact burdens to a significant degree. While part 2 programs will likely experience a burden reduction from the lifting of a consent requirement, the permission may cause an increase in disclosures to public health authorities, resulting in a net impact of no change to burdens. Additionally, to the extent these disclosures are required by other law, the compliance burden is not calculated as a change caused by part 2.

Sections 2.61 Through 2.65 Procedures for Court Orders

The Department lacks sufficient data to estimate the number of instances where the expanded scope of protection from use or disclosure of records against the patient in legal proceedings (including in administrative and legislative forums) would result in increased applications for court orders authorizing the disclosure of part 2 records or testimony.

Section 2.66 Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Investigate or Prosecute a Part 2 Program or the Person Holding the Records

Section 2.66(a)(3) provides specific procedures for investigative agencies to follow upon discovering after the fact that they are holders of part 2 records, such as securing, returning, or destroying the records and optionally seeking a court order under subpart E. Although the existing regulation does not expressly require law enforcement agencies to return or destroy records that it cannot use in investigations or prosecutions against a part 2 program when it does not obtain the required court order, it requires lawful holders to comply with § 2.16 (Security for records). The Department developed the requirements in § 2.66(a)(3) (to return or destroy records that an investigative agency is unable to use or disclose in an investigation or prosecution) to parallel the existing requirements in § 2.16 for programs and lawful holders to establish policies for securing paper and electronic records, removing them, and destroying them. Section 2.66(c) requirements to obtain a court order, obtain information in violation if this part, or to return or destroy the records within a reasonable time (no more than 120 days from discovering it has received part 2 records), would not significantly increase the existing burden for investigative agencies to comply with § 2.16.

Section 2.67 Orders Authorizing the Use of Undercover Agents and Informants To Investigate Employees or Agents of a Part 2 Program in Connection With a Criminal Matter

Section 2.67(c)(4) restricts an investigative agency from seeking a court order authorizing placement of an undercover agent or informant unless it has first exercised reasonable diligence as described by § 2.3(b). This provision serves as a prerequisite that would allow an investigative agency to continue placement of the undercover agent or informant in a part 2 program by correcting an error of oversight if the investigative agency learns after the fact that the undercover agent or informant is in a part 2 program and avoiding the risk of penalties for the violation. The Department anticipates that the added burden for searching SAMHSA's online treatment locator (*FindTreatment.gov*) and a similar state database, and a program's website or physical location, including its Patient Notice or HIPAA NPP to ascertain whether the program provides SUD treatment, would be

minimal, as these activities would normally be included in the course of investigating and prosecuting a part 2 program. The requirement would merely shift the timing of these actions in some cases so that investigative agencies ensure they are completed prior to requesting court approval of an undercover agent or use of an informant. The primary burden on investigative agencies would be to include a statement in an application for a court order after learning of the program's part 2 status after the fact, that the investigator or prosecutor first exercised reasonable diligence to determine whether the program provided SUD treatment. The burden for including this statement within an application for a court order is minimal and could consist of standard language used in each application. Thus, the Department has not calculated specific quantitative costs for compliance.

h. Costs Borne by the Department

This rule has cost impact on HHS. HHS has the primary responsibility to assess the regulatory compliance of covered entities and business associates and part 2 programs. This final rule would extend those responsibilities to part 2 programs. In addition to promulgating the current regulation, HHS would be responsible for developing guidance and conducting outreach to educate the regulated community and the public. The final rule also requires HHS to investigate and resolve complaints and compliance reviews as part of its expanded responsibility for part 2 compliance and enforcements. The Department estimates that implementing the new part 2 enforcement requirements would require two full-time policy employees (or contractors) at the Office of Personnel Management (OPM) General Schedule (GS) GS-14 or equivalent level who will develop regulation, guidance, and national-level outreach. Additionally, the Department estimates needing eight full-time employees (or contractors) for enforcement at a GS-13 or equivalent level to investigate, train investigators, and provide local outreach to regulated entities.³⁶⁶ The

³⁶⁶ To determine the salary rate of the employees at the GS-13 and GS-14 pay scale, the Department used the U.S. OPM's GS classification and pay system and used the Department's General Schedule (Base) annual rates. The Department used the available 2022 data for the estimated costs. In 2022, the salary table for schedule GS-13, step 1 annual rate is \$213,646, including \$106,832 plus 100% for fringe benefits and overhead, and the GS-14, step 1 annual rate is \$252,466, including \$126,233 plus 100% for fringe benefits and overhead. The Department estimated the costs over 5 years based on within-grade step increases based

cost of labor for enforcement of part 2 programs across the ten employees described above amounts to \$2,214,100 in the first year and \$11,808,508 over all five years from 2024 to 2028, including appropriate step increases expected across years. The Department also estimates costs for hiring a contractor to create a breach portal or a part 2 module for the existing HIPAA breach portal. The Department assumes that the costs of hiring each contractor to maintain the breach portal amounts to 5 percent of the annual operation and management funding for the breach portal.³⁶⁷ The initial posting of such breaches is automated, and HHS currently pays a contractor approximately \$13,814 annually to maintain the database to receive reports of breaches from HIPAA covered entities. Under the same assumptions, the Department estimates approximately \$13,814 to hire a second contractor to maintain the database to exclusively receive reports of breaches from part 2 programs. Additionally, HHS drafts and posts summaries of each large breach on the website, using a combination of GS-12, GS-13, GS-14, and GS-15 workers.³⁶⁸ In total, the Department assumes it will take workers 1.5 hours to summarize each breach and that there will be 267 breaches requiring summaries per year, equaling a labor cost of approximately \$32,107 per year. To implement the enforcement requirements, breach portal maintenance, and breach summary reporting, the Department estimates that first year Federal costs will be approximately \$2,260,021 million. The Department estimates that based on the GS within grade step increases for each of the GS-13 and GS-14 employees working to enforce part 2 the Federal costs will be approximately \$12,038,112 million over 5 years. These costs are presented in Table 18 below. The NPRM had not originally included the cost to the Department in the total cost estimate. However, as these costs to the Department are new to establish an

on an acceptable level of performance and longevity (waiting periods of 1 year at steps 1-3 and 2 years at steps 4-6).

³⁶⁷ The Department estimates that the O&M costs of maintaining the portal are \$276,281 in 2022.

³⁶⁸ The Department uses hourly rates for Federal employees from the OPM's GS Base hourly rates for 2022. All workers are assumed to be at step 1. In 2022, GS-12 workers' hourly rate is \$65.46, including \$32.73 plus 100% for fringe benefits and overhead; GS-13 workers' hourly rate is \$77.84, including \$38.92 plus 100% for fringe benefits and overhead; an average rate between GS-14 and GS-15 workers is used, equaling \$100.08, including \$50.04 plus fringe benefits and overhead; and lastly HHS headquarters staff is calculated at the GS-12 step 1 level with Washington, DC locality pay, equaling \$86.06, including \$43.04 plus 100% for fringe benefits and overhead.

enforcement program for part 2, they

have been incorporated into the final costs, presented below.³⁶⁹
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Table 18. Part 2 Federal Costs (2022 dollars)

Federal Cost	Year 1	Year 2	Year 3	Year 4	Year 5
Enforcement Labor Cost	\$2,214,200	\$2,287,908	\$2,361,700	\$2,435,504	\$2,509,296
Cost for Contract to Maintain Breach Portal	\$13,814	\$13,814	\$13,814	\$13,814	\$13,814
Summary Drafting Labor Cost	\$32,107	\$32,107	\$32,107	\$32,107	\$32,107
TOTAL					\$12,038,112

i. Comparison of Benefits and Costs

The final rule results in costs, cost savings, and benefits as described in the

preceding sections. Table 19 presents the 5-year costs and cost savings associated with part 2. Finally, Table 20

provides a narrative description of the non-quantified final rule changes and costs and benefits.

Table 19. Total Part 2 Costs and Savings Over 5-year Time Horizon (2022 dollars).

COST ITEM	5-YEAR COSTS	5-YEAR COST SAVINGS
2.4 Receiving a Complaint	\$191,191	
2.16 Breach Notice	\$7,942,207	
2.22 Patient Notice & Right to Discuss	\$3,118,002	
2.25 Accounting of Disclosures	\$1,228	
2.26 Requests for Restrictions	\$25,096	
2.31 Updating Consent Form	\$1,686,716	
2.32 Updating Disclosure Notice	\$659,027	
2.32 Attaching Consent Form	\$14,735,957	
2.68 Reporting to the Secretary	\$308,630	
Training	\$13,320,1864	
Capital Expenses	\$4,635,891	(\$2,476,388)
Obtaining Consent		(\$64,631,389)
Federal Costs	\$12,038,112	
TOTAL	\$58,662,242	(\$67,107,778)
NET SAVINGS/COSTS		(\$8,445,706)

³⁶⁹ Note, an FY 2024 budget request to support additional enforcement activity is pending. See U.S. Dep't of Health and Human Servs., "Department of

Health and Human Services, Fiscal Year 2024," FY 2024 Budget Justification, General Department

Management, Office for Civil Rights, at 255, <https://www.hhs.gov/sites/default/files/fy-2024-gdm-cj.pdf>.

Table 20. Non-quantified Benefits/Costs for Regulated Entities and Patients.

Regulatory Changes	Costs	Benefits
Add notification of breaches of records by part 2 programs in the same manner the Breach Notification Rule applies to breaches of PHI by covered entities.		Increased opportunity for patients to take steps to mitigate harm. Would provide the same information protections to patients receiving SUD treatment as are afforded to patients that receive other types of health care services.
Change the consent form content requirements and reduce instances where a separate written consent is needed.	Potential loss to patients of opportunity to provide granular consent for each use and disclosure; potential to chill some patients' willingness to access care.	Improved clarity and reduction of paperwork for patients, part 2 programs, covered entities, and business associates.
Align the Patient Notice and the HIPAA NPP.		Improved understanding of patients' rights and covered entities' privacy practices.
Adding right to discuss program's Patient Notice.		Improved understanding of patients' rights & programs' confidentiality practices; improved access to care.
Change the content requirements for the notice accompanying disclosure.		Increased knowledge by patients of the expanded prohibition on use of records against patients in legal proceedings. Improved coordination for certain protections for part 2 records to "follow the record."
Add a new right for patients to request restrictions on uses and disclosures of their records for TPO.		New opportunity for patients to assert their privacy interests to program staff; increased patient control through ability to prevent disclosures to their health plan when patient has paid in full for services. For part 2 programs, likely increase in full payment by patients which would decrease staff

Regulatory Changes	Costs	Benefits
		time spent with billing and claims activities.
Add an accounting of disclosures for TPO.	Potential increased costs to modify information systems to capture required data.	Increased transparency about how records and part 2 information are disclosed for TPO.
Modifications for clarification, readability, or consistency with HIPAA terminology.		Improved understanding by regulated entities, patients, and the public.
Limiting investigative agencies' potential liability for unknowing receipt of part 2 records.		Increased awareness of part 2 obligations for investigative agencies. Opportunity for investigative agencies to pursue action against part 2 programs despite initial procedural errors.
Requiring investigative agencies to report annually to the Secretary if they seek to use records obtained prior to seeking a court order.		Creates transparency and accountability for agencies' use of part 2 records in civil, criminal, administrative, and legislative proceedings.

BILLING CODE 4153-01-C**Consideration of Regulatory Alternatives**

Upon review of public comments on the NPRM, the Department considered alternatives to several proposals and the provisions that are finalized in this rule as explained below.

Section 2.11 Definitions**Lawful Holder**

Although not required by the CARES Act, the Department is finalizing a regulatory definition of the term "lawful holder." We considered expressly excluding family, friends, and informal caregivers from the definition because we understand that these types of informal caregivers are overwhelmingly not professional entities and would not have the means or other resources necessary to meet obligations that part 2 places upon them. For example, § 2.16 requires part 2 programs or other lawful holders to have in place formal policies and procedures to protect against unauthorized disclosures and a patient's family member who receives a record based on consent could not be reasonably expected to comply.

The description of "lawful holder" as a person who has received a part 2 record based on consent means that any person who receives records pursuant to a valid consent could be considered a lawful holder. We believe maintaining the parameters of the definition so it is confined to those who receive records as specified, is clear and unambiguous. To maintain this clarity, the Department believes it more appropriate to carve out an exception in § 2.16 for certain types of lawful holders (*i.e.*, family, friends, and informal caregivers) from those obligations to which they should not reasonably be expected to adhere. As we discuss in preamble, we do expect that these informal caregivers will still exercise some level of caution and care when handling these records.

Section 2.12 Exception for Reporting Suspected Abuse and Neglect

The Department considered for a second time expanding the exception under § 2.12(c)(6) for reporting suspected child abuse and neglect to include reporting suspected abuse and neglect of adults. Such an expansion would be consistent with the HIPAA Privacy Rule permission to report abuse,

neglect, or domestic violence at 45 CFR 164.512(c), and could be beneficial for vulnerable adults, such as persons who are incapacitated or otherwise are unable to make health care decisions on their own behalf. However, § 2.12(c)(6), under the authority of 42 U.S.C. 290dd-2, limits the reporting of abuse and neglect to reporting child abuse and neglect as required by State or local law. Further, section (c) of the authorizing statute also restricts uses of records in criminal, civil, or administrative contexts, which could include investigations by a protective services agency, for example, unless pursuant to a court order or with the patient's consent. Therefore, the Department determined that expanding the exception under § 2.12(c)(6) to include reporting abuse and neglect of adults would exceed the statutory authority although we believe such reporting is needed.

Section 2.16 Security of Records and Notification of Breaches

The Department considered further harmonizing part 2 and the HIPAA regulations by applying the HIPAA Security Rule, or components of it, to

part 2 programs and other lawful holders with respect to electronic part 2 records. A majority of commenters who addressed this issue recommended applying the HIPAA Security Rule to part 2 programs; however, few of these comments were from part 2 programs. Further, the CARES Act did not make the HIPAA Security Rule applicable to part 2 programs. The Department is not finalizing any additional modifications to align the HIPAA Security Rule and part 2 at this time, but will take these comments into consideration in potential future rulemaking.

Breach Notification Obligation for QSOs

The Department considered expressly applying breach notification provisions finalized in paragraph (b) of § 2.16 to qualified service organizations “in the same manner as those provisions apply to a business associate [. . .].” To the extent that QSOs handle unsecured part 2 records on behalf of part 2 programs, the same policy objectives for requiring breach notification would equally apply. Further, to align with the structure of HIPAA, which imposes breach notification obligations on both covered entities and business associates, the Department considered that finalizing a parallel provision would further align the regulations. However, in analyzing title 42, as amended by the CARES Act, Congress was silent on this issue. In comparison, in section 13402(b) of the HITECH Act, Congress expressly extended the obligation of a business associate to notify covered entity in the event of a breach of PHI. This difference leads us to conclude that the requirement for QSOs to report was not intended. However, we expect that part 2 programs are likely to consider adding such requirements to QSO agreements to enable the programs to meet their breach notification obligations.

Section 2.26 Right To Request Restrictions Based on Ability To Pay

Section 290dd–2 of title 42 of U.S.C., as amended by the CARES Act, applied section 13405(c) of the HITECH Act, including the right of a patient to obtain restrictions on disclosures to health plans for services paid in full similar to how the right is structured in the HIPAA Privacy Rule at 45 CFR 164.522 with respect PHI. In response to public comments, the Department considered a more equitable provision that would require part 2 programs to agree to a requested restriction in the case of those who cannot afford to pay for care in full. The Department determined that the amended statute did not grant such authority. The Sense of Congress in the

CARES Act, section 3221(k)(3), provides that: “[c]overed entities should make every reasonable effort to the extent feasible to comply with a patient’s request for a restriction regarding a particular use or disclosure.” Although the Sense of Congress did not include part 2 programs in its urging, we encourage these programs to also make every reasonable effort to fulfill requested restrictions on disclosures for TPO.

Sections 2.31 and 2.32 Tracking Consent and Revocation of Consent

The Department considered alternatives to facilitate the new TPO consent and redisclosure permission for recipients of part 2 records and ensure such records are protected from use and disclosure in proceedings against the patient, absent consent or a court order. The Department further considered how other changes to the scope of a patient’s consent would be tracked or communicated to recipients, such as patient-requested restrictions on disclosures and revocation of consent. We received many comments offering information about current practices, technology capabilities, and different approaches to tracking consent, revocation, and restrictions, as discussed in the preamble, and considered not imposing any new requirements. However, comments that sought no requirement to track the scope of consent provided were from organizations that did not believe that the prohibition on use of records in proceedings against patients should continue to apply to records received by a covered entity or business associate under a TPO consent. We disagree with this view and further, recognize that patients may still provide a consent for disclosures that is not a TPO consent. We considered requiring a copy of consent to be attached to each disclosure without any other option; however, in consideration of the amount of the burden and the available HIE models used to exchange electronic records, we offer an option in new paragraph (b) of § 2.32 for disclosers to provide a clear explanation of the scope of the consent provided. We believe this offers the flexibility needed for health IT systems to exchange needed information about the consent status of an electronic record.

The Department also analyzed how part 2 programs and recipients of records would effectively implement a patient’s revocation of consent and considered adding a requirement for programs to notify recipients when a consent is revoked. Upon consideration of the complexities and burden this

would impose we decided not to create a regulatory requirement, but to explain our expectation in preamble that programs would ensure patients’ revocation rights are respected.

Section 2.52 Adding a Permission To Disclose Records in Limited Data Sets

The Department considered adding a permission to allow part 2 programs to disclose records in the form of a limited data set. The part 2 requirements for a limited data set would have matched those for limited data sets under the HIPAA Privacy Rule (45 CFR 164.504(e)) and would have responded to public comments requesting such a permission for research and public health disclosures of records. However, title 42 refers only to the disclosure of records de-identified to the HIPAA standard at 45 CFR 164.514(b) for public health purposes and this differs from de-identification allowed for a limited data set under 45 CFR 164.514(e). Although the Department is finalizing new standards for public health and research purposes that align with the 45 CFR 164.514(a) and (b), we are not promulgating a standard for limited data sets at this time.

Subpart E Evidentiary Suppression Remedy for Records Obtained in Violation of Part 2

In response to commenters’ concerns about the potential for law enforcement to obtain records through coerced patient consent, we considered creating an express right for patients to request suppression of records obtained in violation of this part for use as evidence in proceedings against them. However, we determined that was unnecessary for two reasons. First, the provision for patients to consent to use and disclosure of records in investigations and proceedings against them is not new—it is covered in § 2.33(a)—thus, newly heightened concern about consent based on changes in this final rule is unwarranted. Second, the prohibition on disclosures based on false consent in § 2.31(c) offers some protection to patients from coerced consent.

Sections 2.66 and 2.67 Preventing Misuse of Records by Investigative Agencies

In response to public comments expressing concern about misuse of records by investigative agencies shielded from liability under the proposed safe harbor, the Department considered describing, in preamble, the expectation that information from records obtained in violation of part 2 cannot be used to apply for a court order for such records. Instead, the

Department added language to §§ 2.66(c)(3) and 2.67(c)(4) to expressly prohibit the use of such information, in regulatory text. The Department believes codifying the prohibition in regulatory text creates an enforceable legal prohibition and more strongly deters investigative agencies from misusing records or information obtained in violation of part 2.

HIPAA NPP

The Department considered finalizing modifications to 45 CFR 164.520 in this final rule and decided not to do so, in part, because of limitations on how often modifications may be made to the HIPAA Privacy Rule.³⁷⁰ Thus, it is necessary to combine changes to the HIPAA NPP with other changes to the HIPAA NPP that are anticipated in the future. Finalizing changes to the HIPAA NPP in this final rule would prevent us from making any further modifications to the HIPAA NPP for one year. We realize this creates a possible gap when covered entities may have changes in policies and procedures that are not reflected in their HIPAA NPP; however, potentially needing to make multiple changes to the HIPAA NPP over a short time span would be equally problematic and confusing to individuals. Additionally, each set of revisions to the HIPAA NPP would add a burden to covered entities for making updates and distributing the HIPAA NPP totaling approximately \$45 million as described in the NPRM.³⁷¹ As explained in preamble, we intend to align compliance dates for any required changes to the HIPAA NPP and part 2 Patient Notice to enable covered entities to make such changes at the same time.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines “small entities” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a

nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000 population. The Department did not receive any public comments on the NPRM small business analysis assumptions and is therefore making no changes to them for this final rule; however, we have updated this analysis of small entities for consistency with revisions to the regulatory impact analysis relating to the costs and cost savings to part 2 programs and covered entities. The Department has determined that roughly 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organization. The Department assumes the part 2 program entities have the same size distribution as health care providers. Therefore, the Department estimates there are 14,459 small entities affected by this rule.³⁷² The SBA size standard for health care providers ranges between a maximum of \$9 million and \$47 million in annual receipts, depending upon the type of entity.³⁷³

The projected costs and savings are discussed in detail in the RIA (section 4.e.). This final rule would create cost savings for regulated entities (part 2 programs and covered entities), many of which are small entities. The Department considers a threshold for the size of the impact of 3 to 5 percent of entity annual revenue as a measure of significant economic impact. The Department estimates the annualized 3 percent discounted net savings, excluding Federal Government costs since they do not apply to covered or small entities, of this rule to be \$4,921,888. Spread across 14,459 small entities, the average savings per small entity are equal to \$340.39. Since even the smallest entities in Sector 62 average over \$55,000 in annual receipts, the projected impact for most of them is well below the 3 to 5 percent threshold.³⁷⁴ Therefore, the Secretary certifies that this final rule would not result in a significant negative impact

³⁷² 14,459 = 16,066 (the number of part 2 program) × 0.9 (90% of all health care providers are small entities).

³⁷³ This range of size standards covers the full list of 6-digit codes in Sector 62—Health Care and Social Assistance. The analysis uses SBA size standards effective as of March 17, 2023. U.S. Small Business Admin., “Table of Small Business Size Standards,” https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

³⁷⁴ The entities in the smallest recorded receipt size category (<\$100,000) average \$56,500 in annual receipts (in 2022 dollars). See U.S. Census, “2017 SUSB Annual Data Tables by Establishment Industry,” <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

on a substantial number of small entities.

C. Unfunded Mandates Reform Act

Section 202(a) of The Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of \$100 million in 1995 dollars, updated annually for inflation. The current threshold after adjustment for inflation is \$177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. The Department does not anticipate that this final rule would result in the expenditure by state, local, and Tribal governments, taken together, or by the private sector, of \$177 million or more in any one year. The final rule, however, present novel legal and policy issues, for which the Department is required to provide an explanation of the need for this final rule and an assessment of any potential costs and benefits associated with this rulemaking in accordance with E.O.s 12866 and 13563. The Department presents this analysis in the preceding sections.

D. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. The Department does not believe that this rulemaking would have any federalism implications.

The federalism implications of the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules were assessed as required by E.O. 13132 and published as part of the preambles to the final rules on December 28, 2000,³⁷⁵ February 20, 2003,³⁷⁶ and January 25, 2013.³⁷⁷ Regarding preemption, the preamble to the final HIPAA Privacy Rule explains that the HIPAA statute dictates the relationship between state law and HIPAA Privacy Rule requirements, and the Privacy Rule’s preemption provisions do not raise federalism issues. The HITECH Act, at section 13421(a), provides that the HIPAA preemption provisions shall apply to the HITECH Act provisions and requirements.

The federalism implications of part 2 were assessed and published as part of

³⁷⁰ See 45 CFR 160.104 (limiting changes by the Secretary to HIPAA standards or implementation specifications to once every 12 months).

³⁷¹ See 87 FR 74216 (Dec. 2, 2022), Table 9b. Privacy Rule Costs and Savings Over 5-year Time Horizon.

³⁷⁵ 65 FR 82462, 82797.

³⁷⁶ 68 FR 8334, 8373.

³⁷⁷ 78 FR 5566, 5686.

the preamble to proposed rules on February 9, 2016.³⁷⁸

The Department anticipates that the most significant direct costs on state and local governments would be the cost for state and local government-operated covered entities to revise consent forms, policies and procedures, providing notification in the event of a breach of part 2 records and drafting, printing, and distributing Patient Notices for individuals with first-time health encounters. The RIA above addresses these costs in detail.

In considering the principles in and requirements of E.O. 13132, the Department has determined that the final rule would not significantly affect the rights, roles, and responsibilities of the States.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999³⁷⁹ requires Federal departments and agencies to determine whether a proposed or final policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department believes that these regulations would positively impact the ability of patients and families to coordinate treatment and payment for health care, particularly for families to participate in the care and recovery of their family members experiencing SUD treatment, by aligning the permission for covered entities and business associates to use and disclose records disclosed to them for TPO purposes with the permissions available in the HIPAA Privacy Rule. The

Department does not anticipate negative impacts on family well-being as a result of this regulation or the separate rulemaking as described.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 104–13), agencies are required to submit to the OMB for review and approval any reporting or recordkeeping requirements inherent in a proposed or final rule, and are required to publish such proposed requirements for public comment. The PRA requires agencies to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department did not receive comments related to the previous notice but has adjusted the estimated respondent burden in this request to reflect revised assumptions based on updated information available at the time of the final rule's publication. This revision resulted in adjusted cost estimates that are

consistent with the RIA presented in this final rule. The estimates covered the employees' time for reviewing and completing the collections required.

As discussed below, the Department estimates a total part 2 program burden associated with all final rule part 2 changes of 672,663 hours and \$50,516,207, including capital costs and one-time burdens, across all 16,066 part 2 programs for 1,864,367 annual patient admissions. On average, this equates to an annual burden of 42 hours and \$3,1444 per part 2 program and 0.36 hours and \$27 per patient admission. Excluding one-time costs that would be incurred in the first year of the final rule's implementation, the average annual burden would be 27 hours and \$1,940 per part 2 program and 0.24 hours and \$17 per patient admission. In addition to program burdens, the Department's final rule would increase burdens on investigative agencies for reporting annually to the Secretary in the collective amount of 759 hours of labor and \$61,726 in costs. This would result in a total burden for part 2 of 672,663 hours in the first year after the rule becomes effective and 439,880 annual burden hours thereafter.

In this final rule, the Department is revising certain information collection requirements and, as such, is revising the information collection last prepared in 2020 and previously approved under OMB control #0930–0092.

Explanation of Estimated Annualized Burden Hours for 42 CFR Part 2

The Department presents, in separate tables below, revised estimates for existing burdens (Table 21), previously unquantified ongoing burdens (Table 22), new ongoing burdens of the final rule (Table 23), and new one-time burdens of the final rule (Table 24).

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³⁷⁸ 81 FR 6987, 7012 (Feb. 9, 2016).

³⁷⁹ Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998).

Table 21. Annualized Estimates of Current Burdens.*

Part 2 Provision	Type of Respondent	Respondents	Responses per Respondent	Total Responses	Average Time per Response (hours)	Total Burden Hours
2.22	Patient Notice	1,864,367 ^a	1	1,864,367	0.021	38,841
2.31	Obtaining Consent for TPO Disclosures	1,864,367	1	1,864,367	0.0833	155,364
2.36	PDMP ^b Reporting	16,066 ^c	176.03	2,828,0501	0.0333	94,268
2.51	Documenting Emergency Tx. Disclosure	16,066	2	32,132	0.167	5,355
2.52	Disclosures for Research - Elec.	125,845 ^d	1	125,845	0.083	10,487
2.52	Disclosures for Research - Paper	13,983 ^e	1	13,983	0.250	3,496
2.53	Disclosures for Audit & Eval. - Elec.	125,845 ^f	1	125,845	0.083	10,487
2.53	Disclosures for Audit & Eval. - Paper	13,983 ^g	1	13,983	0.250	3,496
Total Ongoing Burdens, Currently Approved³⁸⁰				6,868,571		321,794

* Not all decimal places are shown.

- a. Number of annual part 2 program admissions as a proxy for total number of patients.
- b. For more information about PDMPs, *see* <https://store.samhsa.gov/product/In-Brief-Prescription-Drug-Monitoring-Programs-A-Guide-for-Healthcare-Providers/SMA16-4997>.
- c. Total number of part 2 programs.
- d. Estimated number of research disclosures made electronically.
- e. Estimated number of research disclosures on paper.
- f. Estimated number of disclosures for audit and evaluation made electronically.
- g. Estimated number of disclosures for audit and evaluation made on paper.

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As shown in Table 21, the Department is adjusting the currently approved burden estimates to reflect an increase in the number of part 2 programs, from

13,585 to 16,066. The respondents for this collection of information are publicly (Federal, State, or local) funded, assisted, or regulated SUD treatment programs. The estimate of the number of such programs (respondents) is based on the results of the 2020 N-SSATS, which represents an increase of

2,481 program from the 2017 N-SSATS which was the basis for the approved ICR under OMB No. 0930-0335. The average number of annual total responses is based the results of the average number of SUD treatment admissions from SAMHSA's 2019 TEDS as the number of annual patient

³⁸⁰ This refers to approved information collections; however, the burden hours shown are adjusted for the final rule.

admissions by part 2 programs (1,864,367 patients). To accurately reflect the number of disclosures, the Department based some estimates on the number of patients (or a multiple of that number) and then divided by the number of programs to arrive at the number of responses per respondent. The Department based other estimates on the number of programs and then multiplied by the estimated number of disclosures to arrive at the total number of responses.

The estimate in the currently approved ICR includes the time spent with the patient to obtain consent and the time for training for counselors.³⁸¹ The Department is now estimating the time for obtaining consent separately from the burden of training time and applies an average of 5 minutes per patient admission for obtaining consent.

For §§ 2.31, 2.52, and 2.53, the Department is separating out estimates for each provision which were previously reported together and is also adjusting the estimates. For § 2.31, the Department believes that disclosures with written consent for TPO are made for 100 percent of patients; due to the final rule changes to the consent requirements, the Department assumes that part 2 programs would experience a decreased burden from an average of 3 consents per admission to 1 consent. Table 21 reflects 1 consent for each of

the 1,864,367 annual patient admissions (used as a proxy for the estimated number of patients) and a time burden of 5 minutes per consent for a total of 155,364 burden hours. The previously unacknowledged burden of obtaining multiple consents for each patient is shown in Table 22, below.

The Department previously estimated that for §§ 2.31 (consent), 2.52 (research), and 2.53 (audit and evaluation) combined, part 2 programs would need to disclose an average of 15 percent of all patients' records (1,864,367 records \times .15 = 279,655 disclosures). The Department is adjusting its estimates to reflect that 15 percent of patients would have records disclosed without consent for research and audits or evaluations and that this would be divided evenly between the two provisions, resulting in 7.5% of 1,864,367 records (or approximately 139,828 disclosures) for § 2.52 disclosures and the same for § 2.53 disclosures. The Department previously estimated that 10 percent of disclosed records would be disclosed in paper form while the remaining 90 percent would be disclosed electronically. The time burden for disclosing a paper record is estimated as 15 minutes and the time for disclosing an electronic record as 5 minutes. For part 2 programs using paper records, the Department

expects that a staff member would need to gather and aggregate the information from paper records, and manually track disclosures; for those part 2 programs with a health IT system, the Department expects records and tracking information will be available within the system.

For § 2.36, the Department used the average number of opiate treatment admissions from SAMHSA's 2019 TEDS (565,610 admissions) and assumed the PDMP databases would need to be accessed and reported once initially and quarterly thereafter for each patient (565,610 \times 5 = 2,828,050). Dividing the number of opiate treatment admissions by the number of SUD programs results in an average of 35.21 patients per program (565,610 patients \div 16,066 programs) and 176.03 PDMP updates per respondent (35.21 patients/program \times 5 PDMP updates per patient). Based on discussions with providers, the Department believes accessing and reporting to PDMP databases would take approximately 2 minutes per patient, resulting in a total annual burden of 10 minutes (5 database accesses/updates \times 2 minutes per access/update) or 0.166 hours annually per patient. For § 2.51, the time estimate for recordkeeping for a clerk to locate a patient record, record the necessary information and re-file the record is 10 minutes.

Table 22. Annualized Estimate of Previously Unquantified Burden.

Part 2 Provision	Type of Respondent	Respondents	Responses per Respondent	Total Responses	Average Time per Response (hours)	Total Burden Hours
2.31	Obtaining Consent	1,864,367 ^a	2.5	4,660,918	0.083	388,410

a. Annual number of part 2 program admissions as a proxy for number of part 2 patients.

As shown in Table 22, for § 2.31 the Department is recognizing for the first time the burden on part 2 programs to obtain multiple consents for each patient annually. The Department estimates that for each patient admission to a program a minimum of 3 consents is needed for disclosures of records: one each for treatment, payment, and health care operations (1,864,367 \times 3).

As shown in Table 21, a burden is already recognized for obtaining

consent, but the estimate assumed only one consent per admission under the existing regulation and it was combined with estimates for disclosures without consent under §§ 2.52 (research) and 2.53 (audit and evaluation). The Department believes its previous calculations underestimated the numbers of consents obtained annually, and thus the Department views its updated estimate (*i.e.*, adding two consents per patient annually) as acknowledging a previously

unquantified burden. Additionally, recipients of part 2 records that are covered entities or business associates must obtain consent for redisclosure of these records. The Department estimates an average of one-half of patients' records are disclosed to a covered entity or business associate that needs to redisclose the record with consent (1,864,367 \times .5), and this also represents a previously unquantified burden. Together, this would result in an increase of 2.5 consents annually per

³⁸¹ The Department estimated that the amount of time for disclosure to a patient ranged from a low of 3–5 minutes to a high of almost 38 minutes; the

approximately 12-minute estimate used to estimate burden reflected a judgment about the time needed to adequately comply with the legal requirements

and for basic training of counselors on the importance of patient confidentiality.

patient. However, this would be offset by the changes in this final rule which is estimated to result in a reduction in

the number of consents by 2.5 per patient, thus resulting in no change

from the currently approved burden of 1 consent per patient.

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Table 23. Annualized Estimates for Final Rule New Recurring Burdens.

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Total Responses	Average burden hours per Response	Total Burden Hours
Entities Receiving a Complaint	1,864	1	1,864	0.167	331
Individual Notice—Written and E-mail Notice (drafting)	1,170 ^a	1	1,170	0.5	585
Individual Notice—Written and E-mail Notice (preparing and documenting notification)	1,170	1	1,170	0.5	585
Individual Notice—Written and E-mail Notice (processing and sending)	1,170	1,941	2,270,271 ^b	0.008	18,162
Individual Notice—Substitute Notice (posting or publishing)	55	1	55	1	55
Individual Notice—Substitute Notice (staffing toll-free number)	55 ^c	1	55	3.42 ^d	188

Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information)	2,265 ^e	1	2,265	.125 ^f	283
Media Notice	5 ^g	1	5	1.25	7
Notice to Secretary (notice for breaches affecting 500 or more individuals)	5	1	5	1.25	7
Notice to Secretary (notice for breaches affecting fewer than 500 individuals)	1,164 ^h	1	1,164	1	1,164
500 or More Affected Individuals (investigating and documenting breach)	5 ⁱ	1	5.34	50	267
Less than 500 Affected Individuals (investigating and documenting breach) -- affecting 10-499	50 ^j	1	49.58	8	397
Less than 500 Affected Individuals (investigating and documenting	1,115 ^k	1	1114.72	4	4,459

breach) -- affecting <10					
Right to Discuss Patient Notice	18,644 ^l	1	18,644	0.12	2,175
Accounting for Disclosures of Part 2 Records	100 ^m	1	800	0.05	5
Rights to Request Restrictions	1,200 ⁿ	1	1,200	0.1	120
Attach consent form with each disclosure (Paper records disclosed)	186,437 ^o	3	559,310	0.08	46,609
Attach consent form with each disclosure (Electronic records disclosed)	1,677,930 ^p	3	5,033,791	0.01	42,948
Report to the Secretary	506 ^q	1	506	1.5	759
TOTAL			7,892,746		118,086

- a. Total number of breach reports submitted to OCR in 2015 (58,482) multiplied by .02 to represent part 2 breaches.
- b. Average number of individuals affected per breach incident reported in 2015 (113,513,562) multiplied by .02.
- c. All 267 large breaches and all 2,479 breaches affecting 10-499 individuals (2,746) multiplied by 0.2.
- d. This assumes that 10% of the sum of (a) all individuals affected by large breaches in 2015 (113,250,136) and (b) 5% of individuals affected by small breaches ($0.05 \times 285,413 = 14,271$) will require substitute notification. Thus, the Department calculates $0.10 \times (113,250,136 + 14,271) = 11,326,441$ affected individuals requiring substitute notification for an average of 4,125 affected individuals per such breach. The Department assumes that 1% of the affected individuals per breach requiring substitute notice annually will follow up with a telephone call, resulting in 41.25 individuals per breach calling the toll-free number. The Department assumes that call center staff will spend 5 minutes per call, with an average of 41 affected individuals per breach requiring substitute notice, resulting in 3.42 hours per breach spent answering calls from affected individuals.

- e. As noted in the previous footnote, this number equals 1% of the affected individuals who require substitute notification ($0.01 \times 11,326,441 = 113,264$) multiplied by .02 to represent part 2 program breaches.
- f. This number includes 7.5 minutes for each individual who calls with an average of 2.5 minutes to wait on the line/decide to call back and 5 minutes for the call itself.
- g. The total number of breaches affecting 500 or more individuals in 2015, multiplied by .02 to represent the number of part 2 breaches.
- h. The total number of HIPAA breaches affecting fewer than 500 individuals in 2015, multiplied by .02 to represent the number of part 2 breaches.
- i. 267 multiplied by .02.
- j. 2,479 multiplied by .02.
- k. 55,736 multiplied by .02.
- l. The Department estimates that 1 percent of all patients annually would request a discussion of the Patient Notice for an average of 7 minutes per discussion, calculated as $.01 \times 1,864,367$ at the hourly wage of a SUD counselor.
- m. The Department estimates that covered entities annually fulfill 5,000 requests from individuals for an accounting of disclosures of their PHI multiplied by .02 to represent the number of requests from patients for an accounting from part 2 patients.
- n. The Department doubled the estimated number of requests for confidential communications or restrictions on disclosures of PHI per year (to 40,000) due to the effect of the broadened TPO consent and related redisclosure permission and multiplied it by .03 to represent requests from part 2 patients.
- o. Calculated as the number of patient admissions multiplied by the number of paper consent forms that need to be attached (10% of total patient admissions and 3 copies of consent forms each).
- p. Calculated as the number of patient admissions multiplied by the number of electronic consent forms (or an explanation of consent) that need to be attached (90% of total patient admissions and 3 copies of consent forms each).
- q. Estimated number of investigations of programs, used as a proxy for the instances an investigative agency would be in receipt of a record prior to obtaining the required court order.

In Table 23 above, the Department shows an annualized new hourly burden of approximately 94,781 hours due to final rule requirements for receiving complaints, breach notification, accounting of disclosures of records, responding to patient's requests for restrictions on disclosures, discussing the Patient Notice, attaching consent form with each disclosure, and required reporting by investigative agencies. These burdens would be recurring. The estimates represent 2 percent of the total estimated by the Department for compliance with the parallel HIPAA requirements for covered entities. This percentage was calculated by dividing the total number of covered entities by the number of part 2 programs ($16,066/774,331 = .02$). The Department recognizes that this is an overestimate because an unknown proportion of part 2 programs are also

covered entities. As a result of these calculations, the estimated number of respondents and responses is a not a whole number. The totals were based on calculations that included decimals not shown in the table, resulting in different totals than computed in ROCIS for some line items. For § 2.32, the Department estimates a new burden for attaching a consent or a clear explanation of the scope of the consent to each disclosure. The Department estimates that each part 2 program would make three (3) annual disclosures per patient for 1,864,367 patients yearly. The Department also estimates that consent forms would need to be attached to paper disclosures as well as electronic disclosures and assumes ninety percent (90%) of disclosures are received electronically, totaling 5,033,791 consents or explanations of consent attached to electronic disclosures, while the

remaining ten percent (10%) would be received in paper format, totaling 559,310 attached paper disclosures. The Department assumes a receptionist or information clerk would take 5 minutes to attach a consent form for each paper disclosure and 30 second to attach a consent form for each electronic disclosure. This would result in a total recurring burden of 46,609 hours for paper disclosures and 41,948 hours for electronic disclosures.

The total number of responses for the accounting of disclosures has been corrected in the table to show 100, whereas the proposed rule displayed a total of 800. The total in Table 23 also includes the Department's estimates for a recurring annual burden on investigative agencies of 759 hours, relying on previous estimates for the burden of reporting breaches of PHI to the Secretary at 1.5 hours per report.

Table 24. Estimates for Nonrecurring New Burdens.

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Total Responses	Average burden hours per Response	Total Burden Hours
2.04 Complaint Procedures & Nonretaliation-Training (manager)	16,066 ^a	1	16,066	0.75	12,050
2.16 Breach Notice - Training (manager)	16,066	1	16,066	1	16,066
2.22 Patient Notice, incl. right to discuss - Training (counselor)	202,072	1	224,231	0.25	45,058
2.22 Updating Patient Notice (lawyer)	16,066	1	16,066	1	16,066
2.25 Accounting of Disclosures - Training (med. records specialist)	16,066	1	16,066	0.5	8,033
2.26 Requests for Restrictions - Training (receptionist, medical records, & billing)	16,066	3	48,198	0.25	12,050
2.31 Updating Consent Form (lawyer)	16,066	1	16,066	0.66	10,711
2.31 Obtaining Consent - Training (receptionist)	16,066	2	32,132	0.5	16,066
2.32 Updating Notice and Copy of Consent to Accompany Disclosure (manager)	16,066	1	16,066	0.333	5,355

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Total Responses	Average burden hours per Response	Total Burden Hours
Training Specialist's Time	16,066	1	16,066	5	80,330
TOTAL			417,023		232,784

a. Estimated total number of part 2 programs.

As shown in Table 24, the Department estimates one-time burden increases as a result of final rule changes to §§ 2.16, 2.22, 2.31, and 2.32 and due to new provisions §§ 2.25 and 2.26. The nonrecurring burdens are for training staff on the final rule provisions and for updating forms and notices. The Department estimates that each part 2 program would need 5 hours of a training specialist's time to prepare and present the training for a total of 80,330 burden hours.

For § 2.16, the Department estimates that each part 2 program would need to train 1 manager on breach notification requirements for 1 hour, for a total of 16,066 burden hours. For § 2.22, the Department estimates that each program will need 1 hour of a lawyer's time to update the content of the Patient Notice (for a total of 16,066 burden hours) and 15 minutes to train 202,072 part 2 counselors on the new Patient Notice and right to discuss the Patient Notice

requirements (for 56,058 total burden hours).

For § 2.25, the Department estimates that each part 2 program would need to train a medical records specialist on the requirements of accounting of disclosures requirements for 30 minutes, resulting in a total burden of approximately 8,033 hours. For § 2.26, the Department estimates that each part 2 program would need to train three staff (a front desk receptionist, a medical records technician, and a billing clerk (16,066 part 2 programs x 3 staff)) for 15 minutes each on the right of a patient to request restrictions on disclosures for TPO. The base wage rate is an average of the mean hourly rate for the three occupations being trained. This would total approximately 12,050 burden hours.

For § 2.31, each part 2 program would need 40 minutes of a lawyer's time to update the consent to disclosure form (for a total of approximately 10,711

burden hours) and 30 minutes to train an average of 2 front desk receptionists on the changed requirements for consent (for a total of approximately 16,066 burden hours). For § 2.32, the Department estimates that each part 2 program would need 20 minutes of a health care manager's time to update the content of the Notice to Accompany Disclosure with the changed language provided in the final rule, for a total of approximately 5,355 burden hours. This is likely an over-estimate because an alternative, short form of the notice is also provided in regulation, and the language for that form is unchanged such that part 2 programs that are using the short form notice could continue using the same notice and avoid any burden increase.

Explanation of Estimated Capital Expenses for 42 CFR Part 2

BILLING CODE 4153-01-P

Table 25. Capital Expenses for Part 2 Activities.*

45 CFR Breach Section	Cost Elements	Number of Breaches	Average Cost per Breach	Total Breach Cost
164.404	Individual Notice—Postage, Paper, and Envelopes	1,170	\$765.04	\$894,822
164.404	Individual Notice—Substitute Notice Media Posting	55	\$510.06	\$28,012
164.404	Individual Notice—Substitute Notice—Toll-Free Number	55	\$79.10	\$4,344
Total Breach				\$927,178
Part 2 Section	Activity	Number of Notices	Average Cost per Notice	Total Notice Cost
2.22	Printing Patient Notice	932,184	\$0.11	\$99,056
2.31	Printing Consent Form	932,184	\$0.11	\$99,056
2.32	Printing Notice to Accompany Disclosure	186,437	\$0.11	\$19,811
Total Part 2 Forms				\$217,922
TOTAL CAPITAL COSTS				\$1,145,000

* Not all decimal places are shown.

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As shown above in Table 25, part 2 programs would incur new capital costs for providing breach notification. The table also reflects existing burdens for printing the Patient Notice, the Notice to Accompany Disclosure, and Consents. The Department has estimated 50 percent of forms used would be printed on paper, taking into account the notable increase in the use of telehealth services for the delivery of SUD treatment and the expectation that the demand for telehealth will continue.³⁸²

³⁸² See Todd Molfenter, Nancy Roget, Michael Chaple, et al., "Use of Telehealth in Substance Use Disorder Services During and After COVID-19: Online Survey Study," *JMIR Mental Health* (Aug. 2, 2021), <https://mental.jmir.org/2021/2/e25835>.

List of Subjects in 42 CFR Part 2

Administrative practice and procedure, Alcohol use disorder, Alcoholism, Breach, Confidentiality, Courts, Drug abuse, Electronic information system, Grant programs—health, Health, Health care, Health care operations, Health care providers, Health information exchange, Health plan, Health records, Hospitals, Investigations, Medicaid, Medical research, Medicare, Patient rights, Penalties, Privacy, Reporting and recordkeeping requirements, Security measures, Substance use disorder.

Final Rule

For the reasons stated in the preamble, the U.S. Department of Health

and Human Services amends 42 CFR part 2 as set forth below:

Title 42—Public Health

PART 2—CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

- 1. Revise the authority citation for part 2 to read as follows:

Authority: 42 U.S.C. 290dd–2; 42 U.S.C. 290dd–2 note.

- 2. Revise § 2.1 to read as follows:

§ 2.1 Statutory authority for confidentiality of substance use disorder patient records.

Title 42, United States Code, section 290dd–2(g) authorizes the Secretary to prescribe regulations to carry out the purposes of section 290dd–2. Such

regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection 290dd-2(b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of section 290dd-2, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

■ 3. Revise § 2.2 to read as follows:

§ 2.2 Purpose and effect.

(a) *Purpose.* Pursuant to 42 U.S.C. 290dd-2(g), the regulations in this part impose restrictions upon the use and disclosure of substance use disorder patient records (“records,” as defined in this part) which are maintained in connection with the performance of any part 2 program. The regulations in this part include the following subparts:

(1) Subpart B: General Provisions, including definitions, applicability, and general restrictions;

(2) Subpart C: Uses and Disclosures With Patient Consent, including uses and disclosures that require patient consent and the consent form requirements;

(3) Subpart D: Uses and Disclosures Without Patient Consent, including uses and disclosures which do not require patient consent or an authorizing court order; and

(4) Subpart E: Court Orders Authorizing Use and Disclosure, including uses and disclosures of records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders.

(b) *Effect.* (1) The regulations in this part prohibit the use and disclosure of records unless certain circumstances exist. If any circumstance exists under which use or disclosure is permitted, that circumstance acts to remove the prohibition on use and disclosure but it does not compel the use or disclosure. Thus, the regulations in this part do not require use or disclosure under any circumstance other than when disclosure is required by the Secretary to investigate or determine a person’s compliance with this part pursuant to § 2.3(c).

(2) The regulations in this part are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their record than an individual with a substance use disorder who does not seek treatment.

(3) The regulations in this part shall not be construed to limit:

(i) A patient’s right, as described in 45 CFR 164.522, to request a restriction on the use or disclosure of a record for purposes of treatment, payment, or health care operations.

(ii) A covered entity’s choice, as described in 45 CFR 164.506, to obtain the consent of the patient to use or disclose a record to carry out treatment, payment, or health care operations.

■ 4. Revise § 2.3 to read as follows:

§ 2.3 Civil and criminal penalties for violations.

(a) *Penalties.* Any person who violates any provision of 42 U.S.C. 290dd-2(a)–(d), shall be subject to the applicable penalties under sections 1176 and 1177 of the Social Security Act, 42 U.S.C. 1320d-5 and 1320d-6.

(b) *Limitation on criminal or civil liability.* A person who is acting on behalf of an investigative agency having jurisdiction over the activities of a part 2 program or other person holding records under this part (or employees or agents of that part 2 program or person holding the records) shall not incur civil or criminal liability under 42 U.S.C. 290dd-2(f) for use or disclosure of such records inconsistent with this part that occurs while acting within the scope of their employment in the course of investigating or prosecuting a part 2 program or person holding the record, if the person or investigative agency demonstrates that the following conditions are met:

(1) Before presenting a request, subpoena, or other demand for records, or placing an undercover agent or informant in a health care practice or provider, as applicable, such person acted with reasonable diligence to determine whether the regulations in this part apply to the records, part 2 program, or other person holding records under this part. Reasonable diligence means taking all of the following actions where it is reasonable to believe that the practice or provider provides substance use disorder diagnostic, treatment, or referral for treatment services:

(i) Searching for the practice or provider among the substance use disorder treatment facilities in the online treatment locator maintained by the Substance Abuse and Mental Health Services Administration.

(ii) Searching in a similar state database of treatment facilities where available.

(iii) Checking a provider’s publicly available website, where available, or its physical location to determine whether in fact such services are provided.

(iv) Viewing the provider’s Patient Notice or the Health Insurance Portability and Accountability Act (HIPAA) Notice of Privacy Practices (NPP) if it is available online or at the physical location.

(v) Taking all these actions within a reasonable period of time (no more than 60 days) before requesting records from, or placing an undercover agent or informant in, a health care practice or provider.

(2) The person followed all of the applicable provisions in this part for any use or disclosure of the received records under this part that occurred, or will occur, after the person or investigative agency knew, or by exercising reasonable diligence would have known, that it received records under this part.

(c) *Enforcement.* The provisions of 45 CFR part 160, subparts C, D, and E, shall apply to noncompliance with this part in the same manner as they apply to covered entities and business associates for noncompliance with 45 CFR parts 160 and 164.

■ 5. Revise § 2.4 to read as follows:

§ 2.4 Complaints of noncompliance.

(a) *Receipt of complaints.* A part 2 program must provide a process to receive complaints concerning the program’s compliance with the requirements of this part.

(b) *Right to file a complaint.* A person may file a complaint to the Secretary for a violation of this part by a part 2 program, covered entity, business associate, qualified service organization, or lawful holder in the same manner as a person may file a complaint under 45 CFR 160.306 for a violation of the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

(c) *Refraining from intimidating or retaliatory acts.* A part 2 program may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any patient for the exercise by the patient of any right established, or for participation in any process provided for, by this part, including the filing of a complaint under this section or § 2.3(c).

(d) *Waiver of rights.* A part 2 program may not require patients to waive their right to file a complaint under this section or § 2.3 as a condition of the provision of treatment, payment, enrollment, or eligibility for any program subject to this part.

■ 6. Amend § 2.11 by:

■ a. Adding in alphabetical order definitions of “Breach”, “Business associate”, “Covered entity”, “Health

care operations”, “HIPAA”, and “HIPAA regulations”;

■ b. Revising the introductory text in the definition of “Informant”;

■ c. Adding in alphabetical order definitions of “Intermediary”, “Investigative agency”, and “Lawful holder”;

■ d. Revising the definition of “Part 2 program director”;

■ e. Adding a sentence at the end of the definition of “Patient”;

■ f. Revising the definition of “Patient identifying information”;

■ g. Adding in alphabetical order the definition of “Payment”;

■ h. Revising the definition of “Person”;

■ i. Adding in alphabetical order the definition of “Personal representative”;

■ j. Revising paragraph (1) in the definition of “Program”;

■ k. Adding in alphabetical order the definition of “Public health authority”;

■ l. Revising the introductory text and paragraph (2) introductory text and adding paragraph (3) in the definition of “Qualified service organization”;

■ l. Revising the definitions of “Records” and “Substance use disorder”;

■ m. Adding in alphabetical order the definition of “Substance use disorder (SUD) counseling notes”;

■ n. Revising the definitions of “Third-party payer”, “Treating provider relationship”, and “Treatment”;

■ o. Adding in alphabetical order definitions of “Unsecured protected health information”, “Unsecured record”, and “Use”.

The revisions and additions read as follows:

§ 2.11 Definitions.

* * * * *

Breach has the same meaning given that term in 45 CFR 164.402.

Business associate has the same meaning given that term in 45 CFR 160.103.

* * * * *

Covered entity has the same meaning given that term in 45 CFR 160.103.

* * * * *

Health care operations has the same meaning given that term in 45 CFR 164.501.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, as amended by the privacy and security provisions in subtitle D of title XIII of the Health Information Technology for Economic and Clinical Health Act, Public Law 111–5 (“HITECH Act”).

HIPAA regulations means the regulations at 45 CFR parts 160 and 164 (commonly known as the HIPAA

Privacy, Security, Breach Notification, and Enforcement Rules or “HIPAA Rules”).

Informant means a person:

* * * * *

Intermediary means a person, other than a part 2 program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient.

Investigative agency means a Federal, state, Tribal, territorial, or local administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding records under this part.

Lawful holder means a person who is bound by this part because they have received records as the result of one of the following:

(1) Written consent in accordance with § 2.31 with an accompanying notice of disclosure.

(2) One of the exceptions to the written consent requirements in 42 U.S.C. 290dd–2 or this part.

* * * * *

Part 2 program director means:

(1) In the case of a part 2 program that is a natural person, that person.

(2) In the case of a part 2 program that is an entity, the person designated as director or managing director, or person otherwise vested with authority to act as chief executive officer of the part 2 program.

Patient * * * In this part where the HIPAA regulations apply, *patient* means an individual as that term is defined in 45 CFR 160.103.

Patient identifying information means the name, address, Social Security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information.

Payment has the same meaning given that term in 45 CFR 164.501.

Person has the same meaning given that term in 45 CFR 160.103.

Personal representative means a person who has authority under applicable law to act on behalf of a patient who is an adult or an emancipated minor in making decisions related to health care. Within this part, a personal representative would have authority only with respect to patient records relevant to such personal representation.

Program * * *

(1) A person (other than a general medical facility) that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

* * * * *

Public health authority has the same meaning given that term in 45 CFR 164.501.

Qualified service organization means a person who:

* * * * *

(2) Has entered into a written agreement with a part 2 program under which that person:

* * * * *

(3) *Qualified service organization* includes a person who meets the definition of *business associate* in 45 CFR 160.103, paragraphs (1), (2), and (3), for a part 2 program that is also a covered entity, with respect to the use and disclosure of protected health information that also constitutes a “record” as defined by this section.

Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts), and including patient identifying information, provided, however, that information conveyed orally by a part 2 program to a provider who is not subject to this part for treatment purposes with the consent of the patient does not become a record subject to this part in the possession of the provider who is not subject to this part merely because that information is reduced to writing by that provider who is not subject to this part. Records otherwise transmitted by a part 2 program to a provider who is not subject to this part retain their characteristic as records in the hands of the provider who is not subject to this part, but may be segregated by that provider.

Substance use disorder (SUD) means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.

Substance use disorder (SUD) counseling notes means notes recorded (in any medium) by a part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private SUD counseling session or a

group, joint, or family SUD counseling session and that are separated from the rest of the patient's SUD and medical record. *SUD counseling notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Third-party payer means a person, other than a health plan as defined at 45 CFR 160.103, who pays or agrees to pay for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of the patient's family or on the basis of the patient's eligibility for Federal, state, or local governmental benefits.

Treating provider relationship means that, regardless of whether there has been an actual in-person encounter:

(1) A patient is, agrees to be, or is legally required to be diagnosed, evaluated, or treated, or agrees to accept consultation, for any condition by a person; and

(2) The person undertakes or agrees to undertake diagnosis, evaluation, or treatment of the patient, or consultation with the patient, for any condition.

Treatment has the same meaning given that term in 45 CFR 164.501.

* * * * *

Unsecured protected health information has the same meaning given that term in 45 CFR 164.402.

Unsecured record means any record, as defined in this part, that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under Public Law 111–5, section 13402(h)(2).

Use means, with respect to records, the sharing, employment, application, utilization, examination, or analysis of the information contained in such records that occurs either within an entity that maintains such information or in the course of civil, criminal, administrative, or legislative proceedings as described at 42 U.S.C. 290dd–2(c).

* * * * *

■ 7. Amend § 2.12 by:

■ a. Revising paragraphs (a)(1) introductory text, (a)(1)(ii), and (a)(2);

■ b. Revising paragraph (b)(1);

■ c. Revising paragraphs (c)(2), (c)(3) introductory text, (c)(4), (c)(5) introductory text, and (c)(6);

■ d. Revising paragraphs (d)(1) and (2); and

■ e. Revising paragraphs (e)(3), (e)(4) introductory text, and (e)(4)(i).

The revisions read as follows:

§ 2.12 Applicability.

(a) * * *

(1) *Restrictions on use and disclosure.*

The restrictions on use and disclosure in the regulations in this part apply to any records which:

* * * * *

(ii) Contain substance use disorder information obtained by a federally assisted substance use disorder program after March 20, 1972 (part 2 program), or contain alcohol use disorder information obtained by a federally assisted alcohol use disorder or substance use disorder program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use or disclosure.*

The restriction on use or disclosure of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290dd–2(c)) applies to any information, whether or not recorded, which is substance use disorder information obtained by a federally assisted substance use disorder program after March 20, 1972 (part 2 program), or is alcohol use disorder information obtained by a federally assisted alcohol use disorder or substance use disorder program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for the treatment, or making a referral for the treatment.

(b) * * *

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Uniformed Services);

* * * * *

(c) * * *

(2) *Uniformed Services.* The regulations in this part apply to any information described in paragraph (a) of this section which was obtained by any component of the Uniformed Services during a period when the

patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Uniformed Services and within those components of the Department of Veterans Affairs furnishing health care to veterans; and

(ii) Any interchange of that information between such components and the Uniformed Services.

(3) *Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.* The restrictions on use and disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:

* * * * *

(4) *Qualified service organizations.*

The restrictions on use and disclosure in the regulations in this part do not apply to the communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to or on behalf of the program.

(5) *Crimes on part 2 program premises or against part 2 program personnel.*

The restrictions on use and disclosure in the regulations in this part do not apply to communications from part 2 program personnel to law enforcement agencies or officials which:

* * * * *

(6) *Reports of suspected child abuse and neglect.* The restrictions on use and disclosure in the regulations in this part do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program including their use and disclosure for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) * * *

(1) *Restriction on use and disclosure of records.* The restriction on the use and disclosure of any record subject to the regulations in this part to initiate or substantiate criminal charges against a patient or to conduct any criminal investigation of a patient, or to use in any civil, criminal, administrative, or legislative proceedings against a patient, applies to any person who obtains the

record from a part 2 program, covered entity, business associate, intermediary, or other lawful holder, regardless of the status of the person obtaining the record or whether the record was obtained in accordance with subpart E of this part. This restriction on use and disclosure bars, among other things, the introduction into evidence of a record or testimony in any criminal prosecution or civil action before a Federal or state court, reliance on the record or testimony to inform any decision or otherwise be taken into account in any proceeding before a Federal, state, or local agency, the use of such record or testimony by any Federal, state, or local agency for a law enforcement purpose or to conduct any law enforcement investigation, and the use of such record or testimony in any application for a warrant, absent patient consent or a court order in accordance with subpart E of this part. Records obtained by undercover agents or informants, § 2.17, or through patient access, § 2.23, are subject to the restrictions on uses and disclosures.

(2) *Restrictions on uses and disclosures*—(i) *Third-party payers, administrative entities, and others.* The restrictions on use and disclosure in the regulations in this part apply to:

(A) Third-party payers, as defined in this part, with regard to records disclosed to them by part 2 programs or under § 2.31(a)(4)(i);

(B) Persons having direct administrative control over part 2 programs with regard to information that is subject to the regulations in this part communicated to them by the part 2 program under paragraph (c)(3) of this section; and

(C) Persons who receive records directly from a part 2 program, covered entity, business associate, intermediary, or other lawful holder of patient identifying information and who are notified of the prohibition on redisclosure in accordance with § 2.32. A part 2 program, covered entity, or business associate that receives records based on a single consent for all treatment, payment, and health care operations is not required to segregate or segment such records.

(ii) *Documentation of SUD treatment by providers who are not part 2 programs.* Notwithstanding paragraph (d)(2)(i)(C) of this section, a treating provider who is not subject to this part may record information about a SUD and its treatment that identifies a patient. This is permitted and does not constitute a record that has been redisclosed under this part. The act of recording information about a SUD and its treatment does not by itself render a

medical record which is created by a treating provider who is not subject to this part, subject to the restrictions of this part.

* * * * *

(e) * * *

(3) *Information to which restrictions are applicable.* Whether a restriction applies to the use or disclosure of a record affects the type of records which may be disclosed. The restrictions on use and disclosure apply to any records which would identify a specified patient as having or having had a substance use disorder. The restriction on use and disclosure of records to bring a civil action or criminal charges against a patient in any civil, criminal, administrative, or legislative proceedings applies to any records obtained by the part 2 program for the purpose of diagnosis, treatment, or referral for treatment of patients with substance use disorders. (Restrictions on use and disclosure apply to recipients of records as specified under paragraph (d) of this section.)

(4) *How type of diagnosis affects coverage.* These regulations cover any record reflecting a diagnosis identifying a patient as having or having had a substance use disorder which is initially prepared by a part 2 program in connection with the treatment or referral for treatment of a patient with a substance use disorder. A diagnosis prepared by a part 2 program for the purpose of treatment or referral for treatment, but which is not so used, is covered by the regulations in this part. The following are not covered by the regulations in this part:

(i) Diagnosis which is made on behalf of and at the request of a law enforcement agency or official or a court of competent jurisdiction solely for the purpose of providing evidence; or

* * * * *

■ 8. Amend § 2.13 by:

■ a. Revising paragraphs (a), (b), and (c)(1); and

■ b. Removing paragraph (d).

The revisions read as follows:

§ 2.13 Confidentiality restrictions and safeguards.

(a) *General.* The patient records subject to the regulations in this part may be used or disclosed only as permitted by the regulations in this part and may not otherwise be used or disclosed in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, state, or local authority. Any use or disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the use or disclosure.

(b) *Unconditional compliance required.* The restrictions on use and disclosure in the regulations in this part apply whether or not the part 2 program or other lawful holder of the patient identifying information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency or official or other government official, has obtained a subpoena, or asserts any other justification for a use or disclosure which is not permitted by the regulations in this part.

(c) * * *

(1) The presence of an identified patient in a health care facility or component of a health care facility that is publicly identified as a place where only substance use disorder diagnosis, treatment, or referral for treatment is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of this part or if an authorizing court order is entered in accordance with subpart E of this part. The regulations permit acknowledgment of the presence of an identified patient in a health care facility or part of a health care facility if the health care facility is not publicly identified as only a substance use disorder diagnosis, treatment, or referral for treatment facility, and if the acknowledgment does not reveal that the patient has a substance use disorder.

* * * * *

■ 9. Amend § 2.14 by revising paragraphs (a), (b)(1), (b)(2) introductory text, (b)(2)(ii), and (c) to read as follows:

§ 2.14 Minor patients.

(a) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable state law to apply for and obtain substance use disorder treatment, any written consent for use or disclosure authorized under subpart C of this part may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. The regulations in this paragraph (a) do not prohibit a part 2 program from refusing to provide treatment until the minor patient consents to a use or disclosure that is necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a state or local law requiring the program to furnish the service irrespective of ability to pay.

(b) * * *

(1) Where state law requires consent of a parent, guardian, or other person for

a minor to obtain treatment for a substance use disorder, any written consent for use or disclosure authorized under subpart C of this part must be given by both the minor and their parent, guardian, or other person authorized under state law to act on the minor's behalf.

(2) Where state law requires parental consent to treatment, the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under state law to act on the minor's behalf only if:

* * * * *

(ii) The minor lacks the capacity to make a rational choice regarding such consent as determined by the part 2 program director under paragraph (c) of this section.

(c) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a substantial threat to the life or physical well-being of the minor applicant or any other person may be disclosed to the parent, guardian, or other person authorized under state law to act on the minor's behalf if the part 2 program director determines that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of this part to their parent, guardian, or other person authorized under state law to act on the minor's behalf; and

(2) The minor applicant's situation poses a substantial threat to the life or physical well-being of the minor applicant or any other person which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under state law to act on the minor's behalf.

■ 10. Amend § 2.15 by revising the section heading and paragraphs (a) and (b)(2) to read as follows:

§ 2.15 Patients who lack capacity and deceased patients.

(a) *Adult patients who lack capacity to make health care decisions—*(1) *Adjudication by a court.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to make their own health care decisions, any consent which is required under the regulations in this part may be given by the personal representative.

(2) *No adjudication by a court.* In the case of a patient, other than a minor or one who has been adjudicated as lacking the capacity to make health care decisions, that for any period suffers

from a medical condition that prevents knowing or effective action on their own behalf, the part 2 program director may exercise the right of the patient to consent to a use or disclosure under subpart C of this part for the sole purpose of obtaining payment for services from a third-party payer or health plan.

(b) * * *

(2) *Consent by personal representative.* Any other use or disclosure of information identifying a deceased patient as having a substance use disorder is subject to the regulations in this part. If a written consent to the use or disclosure is required, that consent may be given by the personal representative.

■ 11. Revise § 2.16 to read as follows:

§ 2.16 Security for records and notification of breaches.

(a) The part 2 program or other lawful holder of patient identifying information must have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information.

(1) *Requirements for formal policies and procedures.* These policies and procedures must address all of the following:

(i) Paper records, including:

(A) Transferring and removing such records;

(B) Destroying such records, including sanitizing the hard copy media associated with the paper printouts, to render the patient identifying information non-retrievable;

(C) Maintaining such records in a secure room, locked file cabinet, safe, or other similar container, or storage facility when not in use;

(D) Using and accessing workstations, secure rooms, locked file cabinets, safes, or other similar containers, and storage facilities that use or store such information; and

(E) Rendering patient identifying information de-identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a particular patient.

(ii) Electronic records, including:

(A) Creating, receiving, maintaining, and transmitting such records;

(B) Destroying such records, including sanitizing the electronic media on which such records are stored, to render the patient identifying information non-retrievable;

(C) Using and accessing electronic records or other electronic media containing patient identifying information; and

(D) Rendering the patient identifying information de-identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient.

(2) *Exception for certain lawful holders.* Family, friends, and other informal caregivers who are lawful holders as defined in this part are not required to comply with paragraph (a) of this section.

(b) The provisions of 45 CFR part 160 and subpart D of 45 CFR part 164 shall apply to part 2 programs with respect to breaches of unsecured records in the same manner as those provisions apply to a covered entity with respect to breaches of unsecured protected health information.

■ 12. Amend § 2.17 by revising paragraph (b) to read as follows:

§ 2.17 Undercover agents and informants.

* * * * *

(b) *Restriction on use and disclosure of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a part 2 program pursuant to an authorizing court order, may be used or disclosed to criminally investigate or prosecute any patient.

■ 13. Amend § 2.19 by:

■ a. Revising paragraphs (a)(1) and (2);

■ b. Adding paragraph (a)(3);

■ c. Revising paragraphs (b)(1) introductory text, (b)(1)(i) introductory text, (b)(1)(i)(A), and (b)(2).

The addition and revisions read as follows:

§ 2.19 Disposition of records by discontinued programs.

(a) * * *

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party);

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the part 2 program; or

(3) The part 2 program is transferred, retroceded, or reassumed pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5301 *et seq.*, and its

implementing regulations in 25 CFR part 900.

(b) * * *

(1) Records in non-electronic (e.g., paper) form must be:

(i) Sealed in envelopes or other containers labeled as follows: “Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]”.

(A) All hard copy media from which the paper records were produced, such as printer and facsimile ribbons, drums, etc., must be sanitized to render the data non-retrievable.

* * * * *

(2) All of the following requirements apply to records in electronic form:

(i) Records must be:

(A) Transferred to a portable electronic device with implemented encryption to encrypt the data at rest so that there is a low probability of assigning meaning without the use of a confidential process or key and implemented access controls for the confidential process or key; or

(B) Transferred, along with a backup copy, to separate electronic media, so that both the records and the backup copy have implemented encryption to encrypt the data at rest so that there is a low probability of assigning meaning without the use of a confidential process or key and implemented access controls for the confidential process or key.

(ii) Within one year of the discontinuation or acquisition of the program, all electronic media on which the patient records or patient identifying information resided prior to being transferred to the device specified in paragraph (b)(2)(i)(A) of this section or the original and backup electronic media specified in paragraph (b)(2)(i)(B) of this section, including email and other electronic communications, must be sanitized to render the patient identifying information non-retrievable in a manner consistent with the discontinued program’s or acquiring program’s policies and procedures established under § 2.16.

(iii) The portable electronic device or the original and backup electronic media must be:

(A) Sealed in a container along with any equipment needed to read or access the information, and labeled as follows: “Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date];” and

(B) Held under the restrictions of the regulations in this part by a responsible person who must store the container in a manner that will protect the information (e.g., climate-controlled environment).

(iv) The responsible person must be included on the access control list and be provided a means for decrypting the data. The responsible person must store the decryption tools on a device or at a location separate from the data they are used to encrypt or decrypt.

(v) As soon as practicable after the end of the required retention period specified on the label, the portable electronic device or the original and backup electronic media must be sanitized to render the patient identifying information non-retrievable consistent with the policies established under § 2.16.

■ 14. Revise § 2.20 to read as follows:

§ 2.20 Relationship to state laws.

The statute authorizing the regulations in this part (42 U.S.C. 290dd–2) does not preempt the field of law which they cover to the exclusion of all state laws in that field. If a use or disclosure permitted under the regulations in this part is prohibited under state law, neither the regulations in this part nor the authorizing statute may be construed to authorize any violation of that state law. However, no state law may either authorize or compel any use or disclosure prohibited by the regulations in this part.

■ 15. Amend § 2.21 by revising paragraph (b) to read as follows:

§ 2.21 Relationship to federal statutes protecting research subjects against compulsory disclosure of their identity.

* * * * *

(b) *Effect of concurrent coverage.* The regulations in this part restrict the use and disclosure of information about patients, while administrative action taken under the research privilege statutes and implementing regulations in paragraph (a) of this section protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of this part of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes.

■ 16. Revise § 2.22 to read as follows:

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission to a part 2 program or, in the

case that a patient does not have capacity upon admission to understand their medical status, as soon thereafter as the patient attains such capacity, each part 2 program shall inform the patient that Federal law protects the confidentiality of substance use disorder patient records.

(b) *Content of notice.* In addition to the communication required in paragraph (a) of this section, a part 2 program shall provide notice, written in plain language, of the program’s legal duties and privacy practices, as specified in this paragraph (b).

(1) *Required elements.* The notice must include the following content:

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed.

Notice of Privacy Practices of [Name of Part 2 Program]

This notice describes:

- HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED
- YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION
- HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION

YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER NAME OR TITLE] AT [PHONE AND EMAIL] IF YOU HAVE ANY QUESTIONS.

(ii) *Uses and disclosures.* The notice must contain:

(A) A description of each of the purposes for which the part 2 program is permitted or required by this part to use or disclose records without the patient’s written consent.

(B) If a use or disclosure for any purpose described in paragraph (b)(1)(ii)(A) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law.

(C) For each purpose described in accordance with paragraphs (b)(1)(ii)(A) and (B) of this section, the description must include sufficient detail to place the patient on notice of the uses and disclosures that are permitted or required by this part and other applicable law.

(D) A description, including at least one example, of the types of uses and disclosures that require written consent under this part.

(E) A statement that a patient may provide a single consent for all future

uses or disclosures for treatment, payment, and health care operations purposes.

(F) A statement that the part 2 program will make uses and disclosures not described in the notice only with the patient's written consent.

(G) A statement that the patient may revoke written consent as provided by §§ 2.31 and 2.35.

(H) A statement that includes the following information:

(1) Records, or testimony relaying the content of such records, shall not be used or disclosed in any civil, administrative, criminal, or legislative proceedings against the patient unless based on specific written consent or a court order;

(2) Records shall only be used or disclosed based on a court order after notice and an opportunity to be heard is provided to the patient or the holder of the record, where required by 42 U.S.C. 290dd-2 and this part; and

(3) A court order authorizing use or disclosure must be accompanied by a subpoena or other similar legal mandate compelling disclosure before the record is used or disclosed.

(iii) *Separate statements for certain uses or disclosures.* If the part 2 program intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(D) of this section must include a separate statement as follows:

(A) Records that are disclosed to a part 2 program, covered entity, or business associate pursuant to the patient's written consent for treatment, payment, and health care operations may be further disclosed by that part 2 program, covered entity, or business associate, without the patient's written consent, to the extent the HIPAA regulations permit such disclosure.

(B) A part 2 program may use or disclose records to fundraise for the benefit of the part 2 program only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications.

(iv) *Patient rights.* The notice must contain a statement of the patient's rights with respect to their records and a brief description of how the patient may exercise these rights, as follows:

(A) Right to request restrictions of disclosures made with prior consent for purposes of treatment, payment, and health care operations, as provided in § 2.26.

(B) Right to request and obtain restrictions of disclosures of records under this part to the patient's health plan for those services for which the patient has paid in full, in the same manner as 45 CFR 164.522 applies to

disclosures of protected health information.

(C) Right to an accounting of disclosures of electronic records under this part for the past 3 years, as provided in § 2.25, and a right to an accounting of disclosures that meets the requirements of 45 CFR 164.528(a)(2) and (b) through (d) for all other disclosures made with consent.

(D) Right to a list of disclosures by an intermediary for the past 3 years as provided in § 2.24.

(E) Right to obtain a paper or electronic copy of the notice from the part 2 program upon request.

(F) Right to discuss the notice with a designated contact person or office identified by the part 2 program pursuant to paragraph (b)(1)(vii) of this section.

(G) Right to elect not to receive fundraising communications.

(v) *Part 2 program's duties.* The notice must contain:

(A) A statement that the part 2 program is required by law to maintain the privacy of records, to provide patients with notice of its legal duties and privacy practices with respect to records, and to notify affected patients following a breach of unsecured records;

(B) A statement that the part 2 program is required to abide by the terms of the notice currently in effect; and

(C) For the part 2 program to apply a change in a privacy practice that is described in the notice to records that the part 2 program created or received prior to issuing a revised notice, a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for records that it maintains. The statement must also describe how it will provide patients with a revised notice.

(vi) *Complaints.* The notice must contain a statement that patients may complain to the part 2 program and to the Secretary if they believe their privacy rights have been violated, a brief description of how the patient may file a complaint with the program, and a statement that the patient will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, telephone number, and email address of a person or office to contact for further information about the notice.

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.* (i) In addition to the content required by paragraph

(b)(1) of this section, if a part 2 program elects to limit the uses or disclosures that it is permitted to make under this part, the part 2 program may describe its more limited uses or disclosures in its notice, provided that the part 2 program may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted to be made for emergency treatment.

(ii) For the part 2 program to apply a change in its more limited uses and disclosures to records created or received prior to issuing a revised notice, the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The part 2 program must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the patient's rights, the part 2 program's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) *Implementation specifications: Provision of notice.* A part 2 program must make the notice required by this section available upon request to any person and to any patient; and

(1) A part 2 program must provide the notice:

(i) No later than the date of the first service delivery, including service delivered electronically, to such patient after the compliance date for the part 2 program; or

(ii) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(2) If the part 2 program maintains a physical service delivery site:

(i) Have the notice available at the service delivery site for patients to request to take with them; and

(ii) Post the notice in a clear and prominent location where it is reasonable to expect patients seeking service from the part 2 program to be able to read the notice in a manner that does not identify the patient as receiving treatment or services for substance use disorder; and

(iii) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(ii) of this section, if applicable.

(3) Specific requirements for electronic notice include all the following:

(i) A part 2 program that maintains a website that provides information about the part 2 program's customer services or benefits must prominently post its notice on the website and make the notice available electronically through the website.

(ii) A part 2 program may provide the notice required by this section to a patient by email, if the patient agrees to electronic notice and such agreement has not been withdrawn. If the part 2 program knows that the email transmission has failed, a paper copy of the notice must be provided to the patient. Provision of electronic notice by the part 2 program will satisfy the provision requirements of this paragraph (c) when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the part 2 program must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

(iv) The patient who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a part 2 program upon request.

■ 17. Amend § 2.23 by revising the section heading and paragraph (b) to read as follows:

§ 2.23 Patient access and restrictions on use and disclosure.

* * * * *

(b) *Restriction on use and disclosure of information.* Information obtained by patient access to their record is subject to the restriction on use and disclosure of records to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

■ 18. Add § 2.24 to subpart B to read as follows:

§ 2.24 Requirements for intermediaries.

Upon request, an intermediary must provide to patients who have consented to the disclosure of their records using a general designation, pursuant to § 2.31(a)(4)(ii)(B), a list of persons to which their records have been disclosed pursuant to the general designation.

(a) Under this section, patient requests:

(1) Must be made in writing; and
(2) Are limited to disclosures made within the past 3 years.

(b) Under this section, the entity named on the consent form that

discloses information pursuant to a patient's general designation (the entity that serves as an intermediary) must:

(1) Respond in 30 or fewer days of receipt of the written request; and

(2) Provide, for each disclosure, the name(s) of the entity(ies) to which the disclosure was made, the date of the disclosure, and a brief description of the patient identifying information disclosed.

■ 19. Add § 2.25 to subpart B to read as follows:

§ 2.25 Accounting of disclosures.

(a) *General rule.* Subject to the limitations in paragraph (b) of this section, a part 2 program must provide to a patient, upon request, an accounting of all disclosures made with consent under § 2.31 in the 3 years prior to the date of the request (or a shorter time period chosen by the patient). The accounting of disclosures must meet the requirements of 45 CFR 164.528(a)(2) and (b) through (d).

(b) *Accounting of disclosures for treatment, payment, and health care operations.* (1) A part 2 program must provide a patient with an accounting of disclosures of records for treatment, payment, and health care operations only where such disclosures are made through an electronic health record.

(2) A patient has a right to receive an accounting of disclosures described in paragraph (b)(1) of this section during only the 3 years prior to the date on which the accounting is requested.

■ 20. Add § 2.26 to subpart B to read as follows:

§ 2.26 Right to request privacy protection for records.

(a)(1) A part 2 program must permit a patient to request that the part 2 program restrict uses or disclosures of records about the patient to carry out treatment, payment, or health care operations, including when the patient has signed written consent for such disclosures.

(2) Except as provided in paragraph (a)(6) of this section, a part 2 program is not required to agree to a restriction.

(3) A part 2 program that agrees to a restriction under paragraph (a)(1) of this section may not use or disclose records in violation of such restriction, except that, if the patient who requested the restriction is in need of emergency treatment and the restricted record is needed to provide the emergency treatment, the part 2 program may use the restricted record, or may disclose information derived from the record to a health care provider, to provide such treatment to the patient.

(4) If information from a restricted record is disclosed to a health care provider for emergency treatment under paragraph (a)(3) of this section, the part 2 program must request that such health care provider not further use or disclose the information.

(5) A restriction agreed to by a part 2 program under paragraph (a) of this section is not effective under this subpart to prevent uses or disclosures required by law or permitted by this part for purposes other than treatment, payment, and health care operations.

(6) A part 2 program must agree to the request of a patient to restrict disclosure of records about the patient to a health plan if:

(i) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

(ii) The record pertains solely to a health care item or service for which the patient, or person other than the health plan on behalf of the patient, has paid the part 2 program in full.

(b) A part 2 program may terminate a restriction, if one of the following applies:

(1) The patient agrees to or requests the termination in writing.

(2) The patient orally agrees to the termination and the oral agreement is documented.

(3) The part 2 program informs the patient that it is terminating its agreement to a restriction, except that such termination is:

(i) Not effective for records restricted under paragraph (a)(6) of this section; and

(ii) Only effective with respect to records created or received after it has so informed the patient.

■ 21. Revise the heading of subpart C to read as follows:

Subpart C—Uses and Disclosures With Patient Consent

* * * * *

■ 22. Amend § 2.31 by:

■ a. Revising paragraphs (a) introductory text and (a)(2) through (8);

■ b. Adding paragraph (a)(10);

■ c. Redesignating paragraph (b) as paragraph (c);

■ d. Adding a new paragraph (b);

■ e. Revising newly redesignated paragraph (c); and

■ f. Adding paragraph (d).

The revisions and additions read as follows:

§ 2.31 Consent requirements.

(a) *Required elements for written consent.* A written consent to a use or disclosure under the regulations in this

part may be paper or electronic and must include:

* * * * *

(2) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(3) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(4)(i) *General requirement for designating recipients.* The name(s) of the person(s), or class of persons, to which a disclosure is to be made ("recipient(s)"). For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement.

(ii) *Special instructions for intermediaries.* Notwithstanding paragraph (a)(4)(i) of this section, if the recipient entity is an intermediary, a written consent must include the name(s) of the intermediary(ies) and:

(A) The name(s) of the member participants of the intermediary; or
(B) A general designation of a participant(s) or class of participants, which must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being used or disclosed.

(iii) *Special instructions when designating certain recipients.* If the recipient is a covered entity or business associate to whom a record (or information contained in a record) is disclosed for purposes of treatment, payment, or health care operations, a written consent must include the statement that the patient's record (or information contained in the record) may be redisclosed in accordance with the permissions contained in the HIPAA regulations, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.

(5) A description of each purpose of the requested use or disclosure.

(i) The statement "at the request of the patient" is a sufficient description of the purpose when a patient initiates the consent and does not, or elects not to, provide a statement of the purpose.

(ii) The statement, "for treatment, payment, and health care operations" is a sufficient description of the purpose when a patient provides consent once for all such future uses or disclosures for those purposes.

(iii) If a part 2 program intends to use or disclose records to fundraise on its

own behalf, a statement about the patient's right to elect not to receive any fundraising communications.

(6) The patient's right to revoke the consent in writing, except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it, and how the patient may revoke consent.

(7) An expiration date or an expiration event that relates to the individual patient or the purpose of the use or disclosure. The statement "end of the treatment," "none," or similar language is sufficient if the consent is for a use or disclosure for treatment, payment, or health care operations. The statement "end of the research study" or similar language is sufficient if the consent is for a use or disclosure for research, including for the creation and maintenance of a research database or research repository.

(8) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who has been adjudicated as lacking the capacity to make their own health care decisions or is deceased, the signature of a person authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.

* * * * *

(10) A patient's written consent to use or disclose records for treatment, payment, or health care operations must include all of the following statements:

(i) The potential for the records used or disclosed pursuant to the consent to be subject to redisclosure by the recipient and no longer protected by this part.

(ii) The consequences to the patient of a refusal to sign the consent.

(b) *Consent required: SUD counseling notes.* (1) Notwithstanding any provision of this subpart, a part 2 program must obtain consent for any use or disclosure of SUD counseling notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the SUD counseling notes for treatment;

(B) Use or disclosure by the part 2 program for its own training programs in which students, trainees, or practitioners in SUD treatment or mental health learn under supervision to practice or improve their skills in group, joint, family, or individual SUD counseling; or

(C) Use or disclosure by the part 2 program to defend itself in a legal action or other proceeding brought by the patient;

(ii) A use or disclosure that is required by § 2.2(b) or permitted by § 2.15(b); § 2.53 with respect to the oversight of the originator of the SUD counseling notes; § 2.63(a); § 2.64.

(2) A written consent for a use or disclosure of SUD counseling notes may only be combined with another written consent for a use or disclosure of SUD counseling notes.

(3) A part 2 program may not condition the provision to a patient of treatment, payment, enrollment in a health plan, or eligibility for benefits on the provision of a written consent for a use or disclosure of SUD counseling notes.

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through reasonable diligence could be known, by the person holding the records to be materially false.

(d) *Consent for use and disclosure of records in civil, criminal, administrative, or legislative proceedings.* Patient consent for use and disclosure of records (or testimony relaying information contained in a record) in a civil, criminal, administrative, or legislative investigation or proceeding cannot be combined with a consent to use and disclose a record for any other purpose.

■ 23. Revise § 2.32 to read as follows:

§ 2.32 Notice and copy of consent to accompany disclosure.

(a) Each disclosure made with the patient's written consent must be accompanied by one of the following written statements (*i.e.*, paragraph (a)(1) or (2) of this section):

(1) *Statement 1.*

This record which has been disclosed to you is protected by Federal confidentiality rules (42 CFR part 2). These rules prohibit you from using or disclosing this record, or testimony that describes the information contained in this record, in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient, unless authorized by the consent of the patient, except as provided at 42 CFR 2.12(c)(5) or as authorized by a court in accordance with 42 CFR 2.64 or 2.65. In addition, the Federal rules prohibit you

from making any other use or disclosure of this record unless at least one of the following applies:

(i) Further use or disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or as otherwise permitted by 42 CFR part 2.

(ii) You are a covered entity or business associate and have received the record for treatment, payment, or health care operations, or

(iii) You have received the record from a covered entity or business associate as permitted by 45 CFR part 164, subparts A and E.

A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31).

(2) *Statement 2.* “42 CFR part 2 prohibits unauthorized use or disclosure of these records.”

(b) Each disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided.

■ 24. Revise § 2.33 to read as follows:

§ 2.33 Uses and disclosures permitted with written consent.

(a) If a patient consents to a use or disclosure of their records consistent with § 2.31, the following uses and disclosures are permitted, as applicable:

(1) A part 2 program may use and disclose those records in accordance with that consent to any person or category of persons identified or generally designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

(2) When the consent provided is a single consent for all future uses and disclosures for treatment, payment, and health care operations, a part 2 program, covered entity, or business associate may use and disclose those records for treatment, payment, and health care operations as permitted by the HIPAA regulations, until such time as the patient revokes such consent in writing.

(b) If a patient consents to a use or disclosure of their records consistent with § 2.31, the recipient may further disclose such records as provided in subpart E of this part, and as follows:

(1) When disclosed for treatment, payment, and health care operations activities to a covered entity or business associate, such recipient may further disclose those records in accordance with the HIPAA regulations, except for

uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.

(2) When disclosed with consent given once for all future treatment, payment, and health care operations activities to a part 2 program that is not a covered entity or business associate, the recipient may further disclose those records consistent with the consent.

(3) When disclosed for payment or health care operations activities to a lawful holder that is not a covered entity or business associate, the recipient may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent on behalf of such lawful holders.

(c) Lawful holders, other than covered entities and business associates, who wish to redisclose patient identifying information pursuant to paragraph (b)(3) of this section must have in place a written contract or comparable legal instrument with the contractor or voluntary legal representative, which provides that the contractor, subcontractor, or voluntary legal representative is fully bound by the provisions of this part upon receipt of the patient identifying information. In making any such redisclosures, the lawful holder must furnish such recipients with the notice required under § 2.32; require such recipients to implement appropriate safeguards to prevent unauthorized uses and disclosures; and require such recipients to report any unauthorized uses, disclosures, or breaches of patient identifying information to the lawful holder. The lawful holder may only redisclose information to the contractor or subcontractor or voluntary legal representative that is necessary for the contractor, subcontractor, or voluntary legal representative to perform its duties under the contract or comparable legal instrument. Contracts may not permit a contractor, subcontractor, or voluntary legal representative to redisclose information to a third party unless that third party is a contract agent of the contractor or subcontractor, helping them provide services described in the contract, and only as long as the agent only further discloses the information back to the contractor or lawful holder from which the information originated.

■ 25. Amend § 2.34 by revising the section heading and paragraph (b) to read as follows:

§ 2.34 Uses and Disclosures to prevent multiple enrollments.

* * * * *

(b) *Use of information in records limited to prevention of multiple enrollments.* A central registry and any withdrawal management or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not use or redisclose patient identifying information for any purpose other than the prevention of multiple enrollments or to ensure appropriate coordinated care with a treating provider that is not a part 2 program unless authorized by a court order under subpart E of this part.

* * * * *

■ 26. Amend § 2.35 by revising paragraphs (a) introductory text, (a)(1), (b)(3), and (d) to read as follows:

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) *Consent for criminal justice referrals.* A part 2 program may disclose information from a record about a patient to those persons within the criminal justice system who have made participation in the part 2 program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those persons within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole officers responsible for supervision of the patient); and

* * * * *

(b) * * *

(3) Such other factors as the part 2 program, the patient, and the person(s) within the criminal justice system who will receive the disclosure consider pertinent.

* * * * *

(d) *Restrictions on use and redisclosure.* Any persons within the criminal justice system who receive patient information under this section may use and redisclose it only to carry out official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

■ 27. Revise the heading of subpart D to read as follows:

Subpart D—Uses and Disclosures Without Patient Consent

* * * * *

■ 28. Amend § 2.51 by revising paragraph (c)(2) to read as follows:

§ 2.51 Medical emergencies.

* * * *

(c) * * *

(2) The name of the person making the disclosure;

* * * *

■ 29. Amend § 2.52 by:

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1) introductory text, (a)(1)(i), (a)(2), (b) introductory text, (b)(2) and (3), and (c)(1) introductory text;

■ b. Adding paragraph (c)(1)(iii); and

■ c. Removing the second paragraph (c)(2).

The revisions and addition read as follows:

§ 2.52 Scientific research.

(a) *Use and disclosure of patient identifying information.*

Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be used or disclosed for the purposes of the recipient conducting scientific research if:

(1) The person designated as director or managing director, or person otherwise vested with authority to act as chief executive officer or their designee, of a part 2 program or other lawful holder of data under this part, makes a determination that the recipient of the patient identifying information is:

(i) A HIPAA covered entity or business associate that has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with 45 CFR 164.508 or 164.512(i), as applicable;

* * * *

(2) The part 2 program or other lawful holder of data under this part is a HIPAA covered entity or business associate, and the use or disclosure is made in accordance with the requirements at 45 CFR 164.512(i).

* * * *

(b) *Requirements for researchers.* Any person conducting scientific research using patient identifying information obtained under paragraph (a) of this section:

* * * *

(2) Must not redisclose patient identifying information except back to the person from whom that patient identifying information was obtained or as permitted under paragraph (c) of this section.

(3) May include data under this part in research reports only in aggregate form in which patient identifying information has been de-identified in

accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient.

* * * *

(c) * * *

(1) *Researchers.* Any person conducting scientific research using patient identifying information obtained under paragraph (a) of this section that requests linkages to data sets from a data repository(ies) holding patient identifying information must:

* * * *

(iii) Ensure that patient identifying information is not redisclosed for data linkage purposes other than as provided in this paragraph (c).

* * * *

■ 30. Amend § 2.53 by:

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1)(ii), (b) introductory text, (b)(1)(iii), (b)(2)(ii), (c)(1) introductory text, (c)(1)(i), (e)(1) introductory text, (e)(1)(iii), (e)(5) and (6), and (f) heading; and

■ b. Adding paragraph (h).

The revisions and addition read as follows:

§ 2.53 Management audits, financial audits, and program evaluation.

(a) *Records not copied or removed.* If patient records are not downloaded, copied or removed from the premises of a part 2 program or other lawful holder, or forwarded electronically to another electronic system or device, patient identifying information, as defined in § 2.11, may be disclosed in the course of a review of records on the premises of a part 2 program or other lawful holder to any person who agrees in writing to comply with the limitations on use and redisclosure in paragraph (f) of this section and who:

(1) * * *

(ii) Any person which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer or health plan covering patients in the part 2 program, or which is a quality improvement organization (QIO) performing a QIO review, or the contractors, subcontractors, or legal representatives of such person or quality improvement organization; or

* * * *

(b) *Copying, removing, downloading, or forwarding patient records.* Records containing patient identifying information, as defined in § 2.11, may be copied or removed from the premises of a part 2 program or other lawful holder or downloaded or forwarded to

another electronic system or device from the part 2 program's or other lawful holder's electronic records by any person who:

(1) * * *

(iii) Comply with the limitations on use and disclosure in paragraph (f) of this section; and

(2) * * *

(ii) Any person which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer or health plan covering patients in the part 2 program, or which is a quality improvement organization performing a QIO review, or the contractors, subcontractors, or legal representatives of such person or quality improvement organization; or

* * * *

(c) * * *

(1) Activities undertaken by a Federal, state, or local governmental agency, or a third-party payer or health plan, in order to:

(i) Identify actions the agency or third-party payer or health plan can make, such as changes to its policies or procedures, to improve care and outcomes for patients with substance use disorders who are treated by part 2 programs;

* * * *

(e) * * *

(1) Patient identifying information, as defined in § 2.11, may be disclosed under paragraph (e) of this section to any person for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the person agrees in writing to comply with the following:

* * * *

(iii) Comply with the limitations on use and disclosure in paragraph (f) of this section.

* * * *

(5) If a disclosure to a person is authorized under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (e)(2) of this section, the person may further use or disclose the patient identifying information that is received for such purposes to its contractor(s), subcontractor(s), or legal representative(s), to carry out the audit or evaluation, and a quality improvement organization which

obtains such information under paragraph (a) or (b) of this section may use or disclose the information to that person (or, to such person's contractors, subcontractors, or legal representatives, but only for the purposes of this section).

(6) The provisions of this paragraph (e) do not authorize the part 2 program, the Federal, state, or local government agency, or any other person to use or disclose patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation as specified in this paragraph (e).

(f) *Limitations on use and disclosure.*

* * *

(h) *Disclosures for health care operations.* With respect to activities described in paragraphs (c) and (d) of this section, a part 2 program, covered entity, or business associate may disclose records in accordance with a consent that includes health care operations, and the recipient may redisclose such records as permitted under the HIPAA regulations if the recipient is a covered entity or business associate.

■ 31. Add § 2.54 to subpart D to read as follows:

§ 2.54 Disclosures for public health.

A part 2 program may disclose records for public health purposes without patient consent so long as:

(a) The disclosure is made to a public health authority as defined in this part; and

(b) The content of the information from the record disclosed has been identified in accordance with the requirements of 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient.

■ 32. Revise the heading of subpart E to read as follows:

Subpart E—Court Orders Authorizing Use and Disclosure

* * * * *

■ 33. Revise § 2.61 to read as follows:

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a use or disclosure of patient information which would otherwise be prohibited by 42 U.S.C. 290dd-2 and the regulations in this part. Such an order does not compel use or disclosure. A subpoena or a similar legal mandate must be issued to compel use or

disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under the regulations in this part.

(b) *Examples.* (1) A person holding records subject to the regulations in this part receives a subpoena for those records. The person may not use or disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under the regulations in this part.

(2) An authorizing court order is entered under the regulations in this part, but the person holding the records does not want to make the use or disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the use or disclosure. Upon the entry of a valid subpoena or other compulsory process the person holding the records must use or disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of the regulations in this part.

■ 34. Revise § 2.62 to read as follows:

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors, and evaluators.

A court order under the regulations in this part may not authorize persons who meet the criteria specified in §§ 2.52(a)(1)(i) through (iii) and 2.53, who have received patient identifying information without consent for the purpose of conducting research, audit, or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize use and disclosure of records to investigate or prosecute such persons who are holding the records.

■ 35. Amend § 2.63 by revising paragraph (a)(3) to read as follows:

§ 2.63 Confidential communications.

(a) * * *

(3) The disclosure is in connection with a civil, criminal, administrative, or legislative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

* * * * *

■ 36. Amend § 2.64 by revising the section heading and paragraphs (a), (b) introductory text, (d)(2), and (e) to read as follows:

§ 2.64 Procedures and criteria for orders authorizing uses and disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the use or disclosure of patient records or testimony relaying the information contained in the records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the use or disclosure which is sought in the course of a civil, administrative, or legislative proceeding. The application may be filed separately or as part of a pending civil action in which the applicant asserts that the patient records or testimony relaying the information contained in the records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given written consent (meeting the requirements of the regulations in this part) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* A court order under this section is only valid when the patient and the person holding the records from whom disclosure is sought have received:

* * * * *

(d) * * *

(2) The public interest and need for the use or disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a use or disclosure must:

(1) Limit use or disclosure to only those parts of the patient's record, or testimony relaying those parts of the patient's record, which are essential to fulfill the objective of the order;

(2) Limit use or disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit use or disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which use or disclosure of a patient's record, or testimony relaying the contents of the record, has been ordered.

■ 37. Amend § 2.65 by revising the section heading and paragraphs (a), (b) introductory text, (d) introductory text, (d)(2), and (e) to read as follows:

§ 2.65 Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the use or disclosure of patient records, or testimony relaying the information contained in those records, to investigate or prosecute a patient in connection with a criminal proceeding may be applied for by the person holding the records or by any law enforcement or prosecutorial official who is responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws, including administrative and legislative criminal proceedings. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise use or disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought in addition to an order under this section, an order under this section is valid only when the person holding the records has received:

* * * * *

(d) *Criteria.* A court may authorize the use and disclosure of patient records, or testimony relaying the information contained in those records, for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

* * * * *

(2) There is a reasonable likelihood that the records or testimony will disclose information of substantial value in the investigation or prosecution.

* * * * *

(e) *Content of order.* Any order authorizing a use or disclosure of patient records subject to this part, or testimony relaying the information contained in those records, under this section must:

(1) Limit use and disclosure to those parts of the patient's record, or testimony relaying the information contained in those records, which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records or testimony to investigation and prosecution of the extremely

serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit use and disclosure to the fulfillment of only that public interest and need found by the court.

■ 38. Amend § 2.66 by

■ a. Revising the section heading and paragraph (a)(1);

■ b. Adding paragraph (a)(3);

■ c. Revising paragraphs (b), (c), and (d).

The revisions and addition read as follows:

§ 2.66 Procedures and criteria for orders authorizing use and disclosure of records to investigate or prosecute a part 2 program or the person holding the records.

(a) * * *

(1) An order authorizing the use or disclosure of patient records subject to this part to investigate or prosecute a part 2 program or the person holding the records (or employees or agents of that part 2 program or person holding the records) in connection with a criminal or administrative matter may be applied for by any investigative agency having jurisdiction over the program's or person's activities.

* * * * *

(3) Upon discovering in good faith that it received records under this part in the course of investigating or prosecuting a part 2 program or the person holding the records (or employees or agents of that part 2 program or person holding the records), an investigative agency must do the following:

(i) Secure the records in accordance with § 2.16; and

(ii) Immediately cease using and disclosing the records until the investigative agency obtains a court order consistent with paragraph (c) of this section authorizing the use and disclosure of the records and any records later obtained. The application for the court order must occur within a reasonable period of time, but not more than 120 days after discovering it received records under this part; or

(iii) If the agency does not seek a court order in accordance with paragraph (a)(3)(ii) of this section, the agency must either return the records to the part 2 program or person holding the records, if it is legally permissible to do so, within a reasonable period of time, but not more than 120 days after discovering it received records under this part; or

(iv) If the agency does not seek a court order or return the records, the agency must destroy the records in a manner that renders the patient identifying information non-retrievable, within a reasonable period of time, but not more

than 120 days after discovering it received records under this part.

(v) If the agency's application for a court order is rejected by the court and no longer subject to appeal, the agency must return the records to the part 2 program or person holding the records, if it is legally permissible to do so, or destroy the records immediately after notice from the court.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the part 2 program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of those persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order in accordance with paragraph (c) of this section. If a court finds that individualized contact is impractical under the circumstances, patients may be informed of the opportunity through a substitute form of notice that the court determines is reasonably calculated to reach the patients, such as conspicuous notice in major print or broadcast media in geographic areas where the affected patients likely reside.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of § 2.64(e). In addition, an order under this section may be entered only if the court determines that good cause exists. To make such good cause determination, the court must find that:

(1) Other ways of obtaining the information are not available, would not be effective, or would yield incomplete information;

(2) The public interest and need for the use or disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services; and

(3) For an application being submitted pursuant to paragraph (a)(3)(ii) of this section, the investigative agency has satisfied the conditions at § 2.3(b). Information from records obtained in violation of this part, including § 2.12(d), cannot be used in an application for a court order to obtain such records.

(d) *Limitations on use and disclosure of patient identifying information.* (1) An order entered under this section must require the deletion or removal of patient identifying information from any documents or oral testimony made available to the public.

(2) No information obtained under this section may be used or disclosed to conduct any investigation or prosecution of a patient in connection with a criminal matter, or be used or disclosed as the basis for an application for an order under § 2.65.

■ 39. Amend § 2.67 by revising paragraphs (a), (c), (d)(3), and (e) to read as follows:

§ 2.67 Orders authorizing the use of undercover agents and informants to investigate employees or agents of a part 2 program in connection with a criminal matter.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a part 2 program as an employee or patient may be applied for by any investigative agency which has reason to believe that employees or agents of the part 2 program are engaged in criminal misconduct.

* * * * *

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make such good cause determination, the court must find all of the following:

(1) There is reason to believe that an employee or agent of the part 2 program is engaged in criminal activity;

(2) Other ways of obtaining evidence of the suspected criminal activity are

not available, would not be effective, or would yield incomplete evidence;

(3) The public interest and need for the placement of an undercover agent or informant in the part 2 program outweigh the potential injury to patients of the part 2 program, physician-patient relationships, and the treatment services; and

(4) For an application submitted after the placement of an undercover agent or informant has already occurred, that the investigative agency has satisfied the conditions at § 2.3(b) and only discovered that a court order was necessary after such placement occurred. Information from records obtained in violation of this part, including § 2.12(d), cannot be used in an application for a court order to obtain such records.

(d) * * *

(3) Prohibit the undercover agent or informant from using or disclosing any patient identifying information obtained from the placement except as necessary to investigate or prosecute employees or agents of the part 2 program in connection with the suspected criminal activity; and

* * * * *

(e) *Limitation on use and disclosure of information.* No information obtained by an undercover agent or informant placed in a part 2 program under this

section may be used or disclosed to investigate or prosecute any patient in connection with a criminal matter or as the basis for an application for an order under § 2.65.

■ 40. Add § 2.68 to subpart E to read as follows:

§ 2.68 Report to the Secretary.

(a) Any investigative agency covered by this part shall report to the Secretary, not later than 60 days after the end of each calendar year, to the extent applicable and practicable, on:

(1) The number of applications made under §§ 2.66(a)(3)(ii) and 2.67(c)(4) during the calendar year;

(2) The number of instances in which such applications were denied, due to findings by the court of violations of this part during the calendar year; and

(3) The number of instances in which records under this part were returned or destroyed following unknowing receipt without a court order, in compliance with § 2.66(a)(3)(iii), (iv), or (v), respectively during the calendar year.

(b) [Reserved]

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Parts 21, 38, 121, et al.

Airplane Fuel Efficiency Certification; Final Rule

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Parts 21, 38, 121, and 125**

[Docket No.: FAA–2022–0241 Amdt. No. 121–391, 125–75, 38–1, 21–107]

RIN 2120–AL54

Airplane Fuel Efficiency Certification

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action adopts fuel efficiency requirements for certification of certain airplanes. These certification requirements implement the emissions standards adopted by the Environmental Protection Agency (EPA) to allow manufacturers to certify their airplanes for fuel efficiency in the United States. This action also fulfills the FAA's Clean Air Act obligations to enforce implementation of EPA's aircraft emissions standards for greenhouse gas emissions.

DATES: Effective April 16, 2024.

The incorporation by reference of a certain publication listed in this rule is approved by the Director of the Federal Register as of April 16, 2024.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see “How to Obtain Additional Information” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Ralph Iovinelli, Office of Policy, International Affairs, & Environment, Emissions Division (AEE–300), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–3566; email ralph.iovinelli@faa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Purpose of the Regulatory Action*

As a signatory State to the Chicago Convention, the United States must establish minimum standards consistent with those prescribed by the International Civil Aviation Organization (ICAO) on a wide range of aviation-related matters, including aircraft emissions, or file a difference. The United States' adoption of the 2017 ICAO carbon dioxide (CO₂) emission standards for certain airplanes aligns United States law with the ICAO standards.

Moreover, the Clean Air Act Amendments of 1970 (Clean Air Act) direct the U.S. Environmental Protection Agency (EPA) to adopt standards applicable to the emission of any air pollutant from any class of aircraft engines. The Clean Air Act also directs the Secretary of Transportation (and by delegation, the Administrator of the FAA) to implement the standards adopted by the EPA.¹ On January 11, 2021, the EPA published a final rule adopting new domestic airplane greenhouse gas (GHG) emissions standards in 40 Code of Federal Regulations (CFR) part 1030.² As required by the Clean Air Act³, the FAA is implementing those EPA standards through this final rule by adopting new certification regulations in 14 CFR part 38 for fuel efficiency for certain covered airplanes. The applicability of these regulations and the regulatory emissions limits are the same as those adopted by ICAO in its airplane CO₂ emission standards.

This rulemaking establishes fuel efficiency certification requirements for certain subsonic jet airplanes with a maximum takeoff mass greater than 5,700 kilograms and for certain propeller-driven airplanes with a maximum takeoff mass greater than 8,618 kilograms. Under this final rule, an airplane is subject to these certification requirements: (1) at new (original) type certification; (2) upon manufacture of any covered airplane after January 1, 2028; or (3) when a modification to a covered airplane meets change criteria specified in the regulations. This rulemaking excepts from applicability airplanes used for firefighting, amphibious airplanes, airplanes lower than specific masses, reciprocating engine airplanes, non-pressurized airplanes, and certain specialized operations airplanes.

For covered airplanes, a certification applicant must demonstrate that the airplane meets these new part 38 requirements. The new part 38 requirements established by this rulemaking prescribe fuel efficiency

limits, which are the emission standards adopted by the EPA. This rulemaking expresses fuel efficiency limits as maximum permitted fuel efficiency metric (FEM) values that are determined by the maximum takeoff mass of the airplane. Thus, the applicant must determine an FEM value to demonstrate compliance against the applicable fuel efficiency limit. The two certifiable components of the FEM are the specific air range (SAR) and the reference geometric factor (RGF). The SAR represents the distance an airplane can travel per unit of fuel consumed and is determined by direct flight test measurement or use of a validated performance model. The RGF is a representation of airplane fuselage size based on the floor area of pressurized space in an airplane. The technical detail needed to determine the FEM value of an airplane is included in Appendix A to part 38. An applicant must receive FAA approval for all information the applicant uses to calculate the FEM value of an airplane. To comply with part 38, the FEM value must not exceed the airplane's applicable fuel efficiency limit.

In addition, to fully implement the EPA standards through the FAA's certification process, this rulemaking makes corresponding changes to the FAA certification procedures in part 21 to include compliance with part 38 as a certification requirement. Moreover, this rulemaking requires that the FEM value of the airplane, along with other part 38 compliance information, be placed in an FAA-approved section of the flight manual of the airplane.

The FAA's adoption of these certification requirements implements the emissions standards adopted by the EPA, allows manufacturers to certify their airplane for fuel efficiency in the United States, and fulfills the statutory obligations of the FAA under the Clean Air Act. The FAA's promulgation of this Airplane Fuel Efficiency regulation is the final step for the United States in implementing the 2017 ICAO carbon dioxide (CO₂) emission standards for certain airplanes promulgated in Annex 16 Volume III under the Chicago Convention.

B. Changes Made in This Final Rule

The FAA has adopted part 38 and sections of parts 21, 121, and 125 largely as they were proposed in a notice of proposed rulemaking (NPRM) that was published on June 15, 2022.⁴

¹ “The Secretary of Transportation, after consultation with the Administrator, shall prescribe regulations to insure compliance with all standards prescribed under section 7571 of this title by the Administrator. The regulations of the Secretary of Transportation shall include provisions making such standards applicable in the issuance, amendment, modification, suspension, or revocation of any certificate authorized by part A of subtitle VII of title 49 or the Department of Transportation Act.” 42 U.S.C. 7572

² **Federal Register** Vol. 86, No. 6, Final Rule, 40 CFR parts 87 and 1030 “Control of Air Pollution from Airplanes and Airplane Engines: GHG Emission Standards and Test Procedures,” Environmental Protection Agency, pp. 2136–2174.

³ 42 U.S.C. 7571

⁴ **Federal Register** Vol. 87, No. 115, Notice of Proposed Rulemaking, 14 CFR parts 21, 38, 121, and 125 “Airplane Fuel Efficiency Certification,” Federal Aviation Administration, pp. 36076–36091.

The FAA considered the public comments it received on its proposal and the adopted rule reflects consideration of those comments. The FAA received over 60 comments on the NPRM, ranging from suggested typographical and grammatical edits to substantive comments on proposed regulatory text and language in the NPRM preamble. As a result of these comments, the FAA made changes throughout the regulatory text. For instance, the FAA revised the language in the applicability and change criteria sections (§§ 38.1 and 38.19) to clarify the applicability of part 38 to newly built airplanes and modifications to airplanes. These revisions clarify this final rule is not applicable to modifications of in-service airplanes that have not previously shown compliance to part 38 prior to the modification, except for manufacturers who are required to comply with part 38 for in-production airplanes that have not received their first certificate of airworthiness as provided in the applicability section of this rule. The FAA also made edits to several technical requirements in Appendix A (e.g., center of gravity, airplane weight, fuel samples, flight test procedures, and calculations and corrections of test data). Revisions to sections within parts 21 and 121 include: the inadvertent omission of the reference to these new fuel efficiency certification requirements in the certification provisions (§ 21.21), consistency edits (§ 21.93), and correction of an error (§ 121.141).

II. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator.

The Clean Air Act, 42 U.S.C. 7572, authorizes the Secretary of Transportation to implement aviation emission standards adopted by the EPA to insure compliance with the same. Furthermore, 49 CFR 1.83(c) delegates to the FAA Administrator the authority to carry out the functions of this section of the Clean Air Act.

This rulemaking adopts regulations to insure compliance with the standards adopted by the EPA under the Clean Air Act in 40 CFR part 1030 to control the emissions of certain GHG emissions from airplanes. This rulemaking is issued under the authority described in 42 U.S.C. 7572 and 49 CFR 1.83(c).

III. Background

A. General Background

As a signatory State to the Chicago Convention, the United States must establish minimum standards consistent with those prescribed by ICAO or file a difference with ICAO if the United States' standards differ from them in any particular respect. The Committee on Aviation Environmental Protection (CAEP) is a technical committee of the ICAO Council that assists in formulating ICAO policy and adopting Standards and Recommended Practices related to aircraft noise and emissions. The FAA represents the United States on CAEP, attending annual Steering Group meetings and CAEP triennial meetings, and contributing technical expertise to CAEP's many working groups. The EPA serves as an advisor to the United States member of CAEP at the annual and triennial meetings and contributes technical expertise to the FAA and CAEP's working groups on aviation emissions, pollution control technology, and environmental policy. Within CAEP, the FAA assists and advises the EPA on aviation-specific environmental issues, airplane and engine technologies, and airworthiness certification matters.

In 2009, the ICAO Council and its Group on International Aviation and Climate Change (GIACC) developed a "Programme of Action" to limit or reduce the impact of aviation on the climate. The program's "basket of measures" included the reduction of the carbon footprint of international civil aviation, beginning with the development of a technology-based certification standard for CO₂ emissions from subsonic airplanes.

The CO₂ standard-setting process included input from governments, airplane and engine manufacturers, non-governmental environmental organizations, research institutions, and academics worldwide. The standard-setting process occurred in two 3-year phases. The first phase focused on the development of the CO₂ certification requirement (i.e., a CO₂ metric, test procedures, and measurement methodology). The second phase focused on the development of the CO₂ standard itself (i.e., establishing regulatory limits, applicability, and assessments of cost effectiveness). The principles and key criteria that guided the process included the concepts that:

- No certification requirements should be imposed that compromise airplane safety;
- Airplane CO₂ emissions should be reduced through the integration of

fuel efficient technologies in airplane type designs;

- Airplanes that incorporate differing generations of CO₂ reduction technologies should be treated fairly and equitably;
- Any adopted standard should be independent of airplane size, purpose or utilization;
- The metric used should be robust and minimize unintended airplane and system design consequences;
- Any adopted standard should use industry standard practices of measurement and correction; and
- The implementation of any adopted standard should reflect a manageable and appropriate level of resources to be expended by national airworthiness authorities and manufacturers.

In February 2016, CAEP agreed on a new CO₂ emission standard for certain airplanes. ICAO adopted this new standard, set out in Annex 16, Volume III, in March 2017.⁵

In the United States, the Clean Air Act directs the EPA to adopt standards applicable to the emission of any air pollutant from any class of aircraft engines, which in the EPA Administrator's judgment causes, or contributes to, air pollution which may reasonably be anticipated to endanger public health or welfare. The Clean Air Act also directs the Secretary of Transportation (and by delegation, the Administrator of the FAA) to implement the standards adopted by the EPA. The FAA implements these EPA standards by prescribing regulations in title 14 CFR that require the certification of aircraft and aircraft engines to the EPA standards.

On January 11, 2021, the EPA published a final rule⁶ adopting new domestic airplane GHG emission standards in 40 CFR part 1030. In accordance with the Clean Air Act, the FAA is adopting new certification regulations for certain airplanes to insure compliance with the EPA standards. The FAA also supports the adoption of these standards because they are aligned with the principles and key criteria that guided the ICAO process. The applicability of these

⁵ Annex 16 to the Convention on International Civil Aviation, Environmental Protection, Volume III, "Aeroplane CO₂ Emissions," First Edition, July 2017. <https://store.icao.int/collections/annex-16-environmental-protection/products/annex-16-environmental-protection-volume-iii-aeroplane-co2-emissions>.

⁶ Federal Register Vol. 86, No. 6, Final Rule, 40 CFR parts 87 and 1030 "Control of Air Pollution from Airplanes and Airplane Engines: GHG Emission Standards and Test Procedures," Environmental Protection Agency, pp. 2136–2174.

regulations and the regulatory emissions limits in the United States are the same as those adopted by ICAO as its airplane CO₂ emission standard in Annex 16, Volume III.

The FAA, EPA, and ICAO each use different terminology to reference the same standards. In Annex 16 Volume III, ICAO references its standard as CO₂ emissions because the amount of CO₂ emitted is directly proportional to the amount of fuel burned by an airplane at cruise speed and altitude. “Airplane CO₂ emissions” is a commonly used term that fits well within ICAO’s international goals to reduce the carbon footprint of aviation. More specifically, Part II of Annex 16 Volume III is titled “Certification Standard for Aeroplane CO₂ Emissions Based on the Consumption of Fuel.”

Domestically, the EPA issued an endangerment finding for GHG emissions from airplane engines,⁷ which, in turn, required the EPA to issue GHG standards for airplane engines. The EPA rule establishes standards for GHGs in recognition of airplane engine emissions of CO₂ and another GHG, nitrous oxide (N₂O).⁸ The EPA did not set limits on N₂O emissions, noting that they are small and are proportionally reduced as fuel consumption is reduced. Accordingly, the EPA adopted the fuel efficiency metric established by ICAO, which effectively limits both CO₂ and N₂O GHGs emitted by airplane engines.

The FAA describes these same limits and procedures as measures of fuel efficiency, since this final rule prescribes a measurement of airplane performance determined by the SAR parameter to determine fuel efficiency. This measurement is akin to the fuel-burn-based ICAO standard. The FAA intends that the fuel efficiency standards be the same as the standards that the EPA adopted in 40 CFR part 1030.

In summary, it is the FAA’s intent that the three standards—FAA’s fuel efficiency regulations in 14 CFR part 38, the EPA’s GHG emission standards in 40 CFR part 1030, and ICAO’s CO₂ emissions standards—be considered

equivalent for purposes of implementation.

The FAA is making final guidance material for part 38 available at the same time as this final rule and has placed the final Advisory Circular 38 (AC38) in the docket.

B. Summary of the NPRM

On June 15, 2022, the FAA published the NPRM titled “Airplane Fuel Efficiency Certification.” At the same time, the FAA also posted for comment in the NPRM docket draft guidance material for the proposal in the form of a draft AC38.

In its NPRM, the FAA proposed the adoption of the EPA’s GHG standards as fuel efficiency standards for airplanes in a new 14 CFR part 38. The FAA-proposed standards would impose requirements when an applicant seeks type certification. In general, the proposal applied to certain subsonic jet airplanes and certain propeller-driven airplanes above a specified mass. The FAA’s proposal also provided for use of the existing part 11 exemption process.

Importantly, the NPRM provided the requirements for determining the fuel efficiency value for subsonic airplanes at certification. The proposal then established fuel efficiency limits as adopted by the EPA. For an airplane, the fuel efficiency limit would be based on a fuel efficiency value calculated using two primary parameters: the SAR and the RGF. The FAA proposal included an Appendix A, which contained the technical detail needed to determine the FEM value. For an airplane to comply with part 38, under the NPRM, the FEM value could not exceed the applicable fuel efficiency limit.

In addition, to fully implement the EPA standards through the FAA’s certification process, for applicable airplanes the proposal included amendments to part 21 to include compliance with part 38, and to the operating regulations to ensure that flight manuals contained fuel efficiency certification information. The FAA solicited public comments on the NPRM and draft AC38 for a period of 61 days. The comment period on the NPRM closed on August 15, 2022.

C. General Overview of Comments

The FAA received 62 comments on the NPRM and the draft AC38. One of these comments was received and considered after the comment period closed.

Most comments were from individuals. In addition, the agency received comments from several airplane and engine manufacturers and industry groups: Aerospace Industries

Association (AIA), Airbus, Airlines for America (A4A), Airlines Pilots Association (ALPA), Avions de Transport Regional (ATR), Boeing, Embraer S.A. (Embraer), FedEx Corporation (FedEx), General Electric Aviation (GE), General Aviation Manufacturers Association (GAMA), Gulfstream Aerospace Corporation (Gulfstream), Modification and Replacement Parts Association (MARPA), National Business Aviation Association (NBAA), and the Port of Seattle.

The FAA received nine comments generally supporting the rule as proposed. These commenters included ALPA, ATR, Port of Seattle, and some individuals. Fourteen commenters, including Boeing, AIA, A4A, Airbus, FedEx, GE, MARPA, Gulfstream, NBAA, GAMA, Embraer, and some individuals supported the rule generally but offered requests for clarifications, changes, or additional provisions. The FAA received comments from 39 individuals who opposed the proposed rule.

The commenters raised overarching issues on the NPRM related to the FAA’s authority to issue the rule, the applicability of the rule, and potential costs of the rule. Commenters also requested clarifications and raised several technical issues. A discussion of comments requesting specific clarifications, changes, or revisions to the NPRM and the FAA’s responses to these requests is in Section IV, “Discussion of Comments and the Final Rule.”

IV. Discussion of Comments and the Final Rule

The following summarizes the comments received to the NPRM and the FAA’s responses to these comments.

A. FAA’s Part 38 Authority

Comments: Several individuals commented that the proposed rule exceeded the FAA’s authority or was otherwise unnecessary for a wide variety of reasons. Conversely, other commenters indicated the proposed rule is needed to allow manufacturers to certify their airplanes for fuel efficiency in the United States and would fulfill the FAA’s Clean Air Act statutory obligations.

Response: The FAA disagrees with those commenters who indicated that the FAA exceeded its authority or that the rule was unnecessary. The proposed rule falls well within the FAA’s statutory mandate and is required by Section 7572 of the Clean Air Act. The Clean Air Act vests authority to regulate airplane emissions with both the EPA and the FAA. Section 7571 of the Clean

⁷ Federal Register Vol. 81, No. 7, Final Rule, 40 CFR parts 87 and 1068 “Finding that Greenhouse Gas Emissions From Aircraft Cause or Contribute to Air Pollution That May Be Reasonably Be Anticipated To Endanger Public Health and Welfare.” Environmental Protection Agency pp. 54422–54475.

⁸ Both CO₂ and N₂O are constituents of EPA’s defined term “greenhouse gases,” which means an air pollutant that is the aggregate group of six greenhouse gases: CO₂, N₂O, methane, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride. See 40 CFR 1030.105.

Air Act directs the EPA to adopt standards applicable to the emission of any air pollutant from any class of aircraft engines, which in the EPA Administrator's judgment causes, or contributes to, air pollution that may reasonably be anticipated to endanger public health or welfare. Further, the EPA must consult with the FAA on these aircraft engine emissions standards. The EPA adopts these standards in title 40 of the CFR.

After the EPA adopts the standards, section 7572 of the Clean Air Act directs the Secretary of Transportation (and by delegation, the Administrator of the FAA)⁹ to implement the standards adopted by the EPA. The FAA implements these standards by adopting regulations in title 14 of the CFR that allow the certification of aircraft and aircraft engines to the EPA standards. In addition, the proposed rule is consistent with the FAA's own statutes (49 U.S.C. 106) that authorize the Administrator to issue regulations.

On January 11, 2021,¹⁰ the EPA published a final rule adopting GHG emissions standards applicable to certain aircraft engines and airplanes in 40 CFR part 1030. In accordance with the mandate under Section 7572, the FAA adopts this rule through new certification regulations in part 38 for certain airplanes to insure compliance with the EPA standards in 40 CFR part 1030.

B. FAA's Role in Establishing Fuel Efficiency Standards

Comments: Several commenters opined that the proposal was unrealistic or that the FAA was "simply bowing to" the EPA. Others said that the FAA should focus on other matters, such as safety.

Response: As described in the "General Background," the FAA and the EPA both participated heavily in the ICAO working group and CAEP that established ICAO's Aeroplane CO₂ standard. Other entities also provided significant input into the process, including the affected global aviation industry and many other representatives. The standard that ICAO

ultimately established was based on a process that considered views from all participants. This process resulted in the adoption of technology-following certification requirements that also prevent backsliding to less fuel-efficient airplanes. For the same reasons articulated in the principles and key criteria that guided the ICAO standard development process, the FAA supported and continues to support the adoption of the ICAO and EPA standards.

Finally, as described in "FAA's Part 38 Authority," the FAA is statutorily obligated to adopt the EPA standard.

Comments: Other commenters suggested that the goals of the proposed regulation may already be met by the existing body of regulations or that industry was already incentivized to achieve fuel efficiency through market forces or otherwise. Some suggested that the industry had already achieved low emissions.

Response: The CO₂ standard-setting process at ICAO included input from many stakeholders, including airplane and engine manufacturers. In addition, the FAA received comments from several airplane and engine manufacturers, including Boeing, Gulfstream, Airbus, GE, Embraer, and ATR, as well as industry groups that represent the broader aviation manufacturers and airlines such as GAMA, AIA, A4A, and NBAA. In their comments on the proposed rule, these entities recognized the domestic and international need of expeditiously adopting these standards in order to establish a global fuel efficiency certification scheme for airplanes. The aviation industry has shown strong support for the standard, which is the first aviation standard aimed at improving airplane fuel efficiency and reducing CO₂ emissions.

C. Consideration of Other Alternatives

Comment: A number of comments went beyond the scope of the proposed rule to suggest that the FAA should instead consider alternative means of achieving decreased CO₂ emissions, such as adding a tax on fuel sales; increasing airplane registration fees; changing flight procedures; creating incentives to encourage operators to purchase newer, more fuel-efficient airplanes; restricting business jets; developing alternative fuels; or increasing the availability of alternative fuels. Other commenters indicated that the rule was not going far enough to improve fuel efficiency.

Response: The FAA reiterates that part 38 is consistent with the FAA's authority under its own statutes and the

Clean Air Act. In particular, the purpose of this rule is to implement EPA's GHG standards through the FAA certification process. Comments received requesting that FAA take an alternative approach to address fuel efficiency are not within the scope of the proposed rule.¹¹

Comment: Other commenters were concerned that the proposed rule would result in manufacturers' transitioning to alternative fuels, such as biofuels, or wanted clarity on the applicability of the proposed rule to hybrid airplanes or airplanes using alternative fuels.

Response: This rule is a technology-based standard, aiming at measuring the performance of the airplane in terms of fuel efficiency, predicated on the ability of manufacturers to improve engine propulsion efficiency, aerodynamics, and airplane weight—all elements of the SAR parameter in the FEM. Neither the SAR nor the RGF parameters are affected by the type of fuel used in the airplane. Therefore, the FEM value does not change based on the fuel used in the airplane.

As a general matter, the rule could apply to any airplanes meeting the applicability criteria of § 38.1, including hybrids or those using alternative fuels as long as those fuel(s) meet the applicable specifications in Appendix A. The FAA wants to clarify that the use of alternative fuels does not exempt covered airplanes from compliance with this rule.

D. General Applicability (§ 38.1(a) and (b))

In the NPRM, the FAA proposed that part 38 would apply to certain subsonic jet airplanes and propeller-driven airplanes at three applicability points. These three points are airplanes (1) receiving original type certification on or after January 11, 2021; (2) manufactured after January 1, 2028, regardless of the date of type certification; and (3) type-certificated before the applicable compliance date but where a modification is made that would affect the fuel efficiency of the airplane after January 1, 2023.

1. Discussion of Final Rule

The FAA adopts the applicability requirements for part 38 in § 38.1(a) and

⁹ Boeing commented that the proposed rule should update the DOT regulations in 49 CFR 1.83(c) that delegate this authority to the FAA Administrator to reflect the new 40 CFR part 1030. Paragraph 1.83(c) delegates to FAA the authority to implement the standards adopted by the EPA under 42 U.S.C. 7572. The FAA does not have the authority to amend 49 CFR 1.83(c) but will raise the issue to DOT.

¹⁰ Federal Register Vol. 86, No. 6, Final Rule, 40 CFR parts 87 and 1030 "Control of Air Pollution from Airplanes and Airplane Engines: GHG Emission Standards and Test Procedures," Environmental Protection Agency, pp. 2136–2174.

¹¹ In *California v. EPA*, a number of states and environmental organizations challenged EPA's adoption of the standards in 40 CFR part 1030. The District of Columbia Circuit Court of Appeals held that the rule was within EPA's authority under 42 U.S.C. 7571 and that the agency reasonably explained its decision to harmonize its regulation with the ICAO standards. The Court also held that as the EPA had made the policy choice to align with ICAO standards, the EPA did not have a need to examine alternatives departing from the ICAO standards. 72 F.4th 308 (D.C. Cir. 2023).

(b). These paragraphs remain largely as proposed and have the same applicability as the EPA regulations. These paragraphs continue to provide for the applicability of these standards to certain subsonic jet airplanes and propeller-driven airplanes at three applicability points. After consideration of public comments, the FAA is revising the regulation to clarify the applicability of part 38 to the currently flying in-service airplanes as well as to proposed modifications to covered¹² airplanes that have received their type certificate. The regulation was also revised to make some other non-substantive changes to the text. These changes are discussed in this section.

As developed by ICAO, the standards adopted by the EPA include three occasions on which an airplane becomes subject to the 40 CFR 1030 standards. These same applicability points are included in § 38.1(a) and (b): (1) at new (original) type certification; (2) the manufacture of any covered airplane after January 1, 2028; or (3) a modification to a covered airplane that meets the change criteria of § 38.19. These change criteria pertaining to airplane modifications are described in further detail in § 38.19. The applicability points include:

- *New (Original) Type Certification Applicability:* Paragraphs 38.1(a)(1)–(3) describe airplanes whose applications for original type certification were submitted after January 11, 2021. Although the ICAO standard on which these regulations are based was effective on January 1, 2020, for certifications of new type designs, the effective date of the EPA regulation was January 11, 2021, for certifications of new type designs. Except for the effective date, the EPA and the FAA regulations have the same applicability as the ICAO standard. The difference in effective dates between the ICAO and EPA standards has no practical effect in the United States. In the twelve months between the effective date of the ICAO standard and the effective date of the EPA standards, the FAA received no applications for new type certification that would meet the applicability criteria of this rule. Although EPA's GHG emissions standards are now applicable in the United States through 40 CFR part 1030, the FAA did not

receive an application for new type certification before the adoption of either EPA's rule or the FAA's rule. Once an airplane is type-certificated for fuel efficiency in accordance with this rule, all airplanes produced under that type certificate must comply with the fuel efficiency standards.

- *Manufacture of covered airplanes after January 1, 2028:* Paragraphs 38.1(a)(6)–(7) describe the second instance of applicability for covered airplanes manufactured after January 1, 2028. These paragraphs address covered airplanes that are newly built after January 1, 2028, regardless of the date of type certification. Airplanes manufactured after this date would not be eligible for a first certificate of airworthiness unless compliance with part 38 has been shown.

- *A modification to a covered airplane that meets the change criteria of § 38.19:* Paragraphs 38.1(a)(4)–(5) address modifications to covered airplanes whose type designs were not certified under this rule, where an application by the type certificate holder for a type design change is submitted on or after January 1, 2023, and the first certificate of airworthiness is issued with the modified type design that exceeds the change criteria in § 38.19(c). In determining applicability under these paragraphs, a certification applicant must consider § 38.1(b), which addresses modifications made to covered airplanes and directs the reader to the change criteria in § 38.19. See section IV.N for a discussion on the change criteria in § 38.19.

As noted, the FAA made a few non-substantive changes to the applicability provisions. The FAA added levels of designation to paragraph (a)(1) at the suggestion of the **Federal Register** to help clarify the two independent applicability provisions in § 38.1(a)(1). The FAA also fixed a minor typographical error in § 38.1(a)(6)(ii) and changed the order of the agencies identified in § 38.1(a)(4) to reflect that the FAA is issuing this rule.

2. Public Comments and FAA Response

Comments: Multiple commenters, such as A4A, AIA, Boeing, Airbus, FedEx, NBAA, and some individuals, requested clarification that the rule would not apply to in-service airplanes, consistent with the related EPA regulation and the applicable ICAO standard. These comments, summarized in the following sentences, included specific statements and questions related to the applicability of the rule to current in-service airplanes and modifications to such airplanes. Boeing requested clarity that individual in-

service airplanes, whose type designs have not been previously certificated to part 38, and to which modifications are made by the owners/operators or other third parties, do not need to demonstrate compliance with part 38. Similarly, some of the commenters, including A4A, Airbus, and Boeing, requested that the FAA clarify the part 38 applicability provisions regarding modified type designs and modified versions of airplanes to more clearly state that part 38 applies only when a type-certificate holder changes the type design of an airplane mid-production by applying for FAA approval of a modified type design. To clarify these concepts, the AIA, A4A, Airbus, and Boeing specifically requested that the FAA modify § 38.1(a)(4)(iii) and (a)(5)(iii) to add “by the holder of the type certificate” to explain that a third party would not be required to show compliance to part 38 when requesting a supplemental type certificate that aims to modify one or more individual in-service airplanes.

In addition, Airbus requested that the FAA clarify the regulatory text in § 38.1(b) by changing “prior version” to “prior non-modified version” to emphasize that the prior version of the airplane is the one that does not include the modification.

Response: The FAA intends this rule to have the same applicability as the related EPA regulation and the ICAO standard. As such, this final rule is not applicable to current in-service airplanes. Where a type certificate holder submits an application for a change in type design after January 1, 2023, and the change meets the requirements of § 38.19(c), part 38 will apply to a newly built airplane incorporating this change in order to receive its first certificate of airworthiness. After January 1, 2028, part 38 will apply to all newly built airplanes receiving their first certificate of airworthiness.

The FAA recognizes that determining the applicability of this rule to a specific airplane requires consideration of multiple sections in part 38. Although § 38.1 addresses applicability in general, when an applicant requests a change in type design, it must also consider § 38.19's change criteria to determine the applicability of part 38. Sections 38.1(a)(1) through (3) address newly built airplanes whose applications for original type certification were submitted after the specified dates. Sections 38.1(a)(4) and (5) provide applicability requirements for a modified version of an airplane whose type design was not certificated under part 38. Further, § 38.1(a)(4) and (5)

¹² For the purpose of FAA's final rule, “covered airplanes” are defined the same as EPA's definition in their final rule: “Civil subsonic jet airplanes (those powered by turbojet or turbofan engines and with a MTOM greater than 5,700 kilograms), as well as larger civil subsonic propeller driven airplanes (those powered by turboprop engines and with a MTOM greater than 8,618 kilograms).” 86 FR 2136 (Jan. 11, 2021).

relate to a newly built airplane, receiving its first certificate of airworthiness, based on a type design change submitted by the type certificate holder on or after January 1, 2023, that exceeds the change criteria in § 38.19(c). On or after January 1, 2028, all newly built covered airplanes that meet the requirements of § 38.1(a)(6) and (7) must comply with part 38 to receive their first certificate of airworthiness.

Section 38.1(b) makes the important connection to the § 38.19 change criteria. In § 38.1(b), part 38 applies to an airplane where an applicant requests a change in type design that meets the change criteria of § 38.19. Airplanes that have demonstrated compliance to this rule (*i.e.*, those that do not fall in § 38.1(a)(4) and (5)) and subsequently undergo modifications will need to re-demonstrate compliance according to the change criteria shown in § 38.19(a) and (b).

With the applicability context described in the previous paragraphs, the FAA agrees to revise the proposed §§ 38.1 and 38.19 to clarify part 38 applicability to individual in-service airplanes and modifications to airplanes. The FAA recognizes that § 38.1(a)(4)(iii) and (5)(iii) in the NPRM may have been interpreted, as commenters suggested, to require compliance with part 38 for any modifications to an airplane, even a currently in-service airplane. The FAA does not intend this applicability. This final rule slightly updates these paragraphs to clarify that this specific set of applicability requirements are for applications for a change in type design made by the type certificate holder. Specifically, in response to comments requesting clarity on modifications to airplanes under these specific applicability requirements, this rule revises § 38.1(a)(4)(iii) and (5)(iii) to state that compliance is required when “an application by the type certificate holder for a type design change is submitted on or after January 1, 2023.” In combination with the rest of the requirements under § 38.1(a)(4) and (5), the part 38 now reads clearly that it does not apply to a type design change application for a currently in-service airplane that has not previously shown compliance to part 38. Only a newly built airplane with a change in type design by the type certificate holder, applied for on or after January 1, 2023, and exceeding change criteria in § 38.19(c), would be required to comply with part 38. Therefore, the final rule clarifies that part 38 does not apply to currently in-service airplanes, including modifications, and instead focuses on

newly built airplanes that incorporate modifications.

Further, in proposed § 38.1(a)(4)(iv) and (a)(5)(iv), the words “for an airplane built” were redundant with the introductory text of § 38.1(a)(4) and (5), which already stated, “A subsonic jet airplane—” and “A propeller-driven airplane—”, respectively. To correct this redundancy, this final rule removes “for an airplane built” from § 38.1(a)(4)(iv) and (a)(5)(iv). Also, this change is consistent with other changes FAA made to § 38.1(a)(4) and (5) to clarify to the applicability. This change does not alter the meaning of the paragraph.

For consistency with and to fully respond to the comments on § 38.1(a), the FAA updates the proposed § 38.1(b) to reflect that part 38 applies to modifications that are based on an application for a change in type design and meet the change criteria of § 38.19. As part of these updates, the FAA moves the § 38.19 reference earlier in the paragraph to incorporate the change criteria more clearly in § 38.1(b). Also, the FAA revises § 38.1(b) to explicitly state that the applicability is tied to an application for a change in the type design. This better aligns with the text of § 38.1(a)(4) and (5).

In response to Airbus’ request that to change “prior version” to “prior non-modified version,” the FAA recognizes that “prior version” of an airplane may not have been described with sufficient detail. Based on these considerations, this rule also revises § 38.1(b) for consistency with § 38.1(a) to more accurately describe the state of an airplane before or after modifications, rather than using “prior version,” and to highlight the connection to the change criteria in § 38.19.

Finally, because § 38.19(b) and (c) also use “prior version,” this rule makes similar consistency changes to these paragraphs.

In summary, these edits to §§ 38.1(a) and (b) and 38.19(b) and (c) clarify that part 38 does not apply to current in-service airplanes.

Comments: Airbus, A4A, and Boeing also recommended that table 1 in the NPRM be clarified to avoid the implication that part 38 be applied to in-service airplanes.

Response: In lieu of providing an updated table 1 from the NPRM to provide a quick reference for applicability with examples, the FAA has provided a much more detailed discussion here to clarify applicability of part 38 to in-service airplanes in this section.

Comments: Similar to comments requesting clarity on prior version of an airplane, Boeing, AIA, and A4A

requested a definition of “subsequent version,” a term that appears in § 38.19, to clarify that modifications to individual in-service airplanes do not require application of the fuel efficiency standards.

Response: This rule’s changes to § 38.1 address the fact that current in-service airplanes, or modification to such airplanes, do not require compliance with this rule. Therefore, the FAA does not see a need to add a definition for the term “subsequent version.”

Comments: Boeing requested that the FAA add a definition of “modified type design,” which is used in § 38.1(a)(4)(iv) and (5)(iv), because it was concerned that the lack of a definition could create potential ambiguity when the text is read together with the well-established aircraft certification regulations in part 21 that address “changes in type design.”

Response: The FAA notes that the term “modified type design” in the context of § 38.1(a)(4)(iv) and (5)(iv), where it appears, refers to the final modified configuration of an airplane receiving its first certificate of airworthiness.

The FAA is using the word modified for consistency with EPA’s regulations. For the purposes of part 38, the FAA uses the words “changed” and “modified” interchangeably.

Comment: Airbus recommended that the four (4) applicability requirements listed under § 38.1(a)(4) and (a)(5) should be joined by adding the conjunction “and” after each individual requirement to clarify that applicability to this rule consists of all four requirements in total.

Response: The FAA reviewed the grammatical structure of § 38.1(a)(4) and (a)(5). As proposed, the four applicability requirements listed under each of these sections are separated by a semicolon in a list from (i) to (iv) with the conjunction “and” between the final two provisions (iii) and (iv), signifying that the “and” applies to all requirements in this list. This format follows the Office of the Federal Register (OFR) formatting practices, and, therefore, the repetition of “and” between each requirement is not required. The FAA believes this is the correct structure and will not incorporate Airbus’s recommendation to add an “and” after each requirement.

Comment: Airbus further commented on several items such as changing the following text from the proposed rule: “. . . an application . . .” to “. . . the application . . .” in paragraph (a)(4)(iii); “. . . type design is submitted . . .” to “. . . type design was submitted . . .” in paragraph (a)(4)(iii);

and “. . . for an airplane built . . .” to “. . . for that airplane built . . .” in paragraph (a)(4)(iv).

Response: The FAA does not agree with these suggestions. The FAA wrote this rule to apply to a wide range of civil airplanes and changing words to “that airplane” or “the application” adds a level of specificity that is not needed for this rule. The suggested change to “for that airplane built with” is not necessary because the FAA removed this phrase from §§ 38.1(a)(4)(iv) and (a)(5)(iv) in response to previously addressed comments. Regarding the change from “is” to “was,” the FAA notes that the verb tense of this rule is written in present tense.

Comment: Airbus commented on § 38.1(a)(6) and (a)(7) that the words “An individual . . .” should be added to the beginning of these applicability paragraphs to reinforce that these requirements apply to individual airplanes. Airbus states this would be similar to the applicability language in ICAO Annex 16 Vol III, Part II, Chapter 2, § 2.1.1(f)&(g).

Response: The applicability language in § 38.1(a)(6) and (a)(7) has the same meaning as the ICAO Annex 16 Vol III language even if the terminology is slightly different. The applicability language in § 38.1(a)(6) and (a)(7) is written in singular form starting with: “A subsonic jet airplane . . .” and “A propeller-driven airplane . . .” that has “Its first certificate of airworthiness issued on or after January 1, 2028.” The word “a” already places the subject in singular form that clearly represents an individual airplane, which is consistent with the ICAO Annex 16 Vol III. For these reasons, it is not necessary to reinforce that these paragraphs apply to “individual” airplanes.

Comment: The GAMA commented that the applicability requirements for propeller-driven airplanes with maximum takeoff mass (MTOM) greater than 8,618 kilograms (kg), as used in the proposed rule, could include airplanes with maximum takeoff weight (MTOW) greater than 18,999.45 lbs when 8,618 kilograms are converted to pounds. The GAMA noted that the mathematical conversion of an MTOM of 8,618 kg equates to 18,999.45 lbs, which is less than what is used for the MTOW limits of parts 21 and 23 for normal category airplanes. Therefore, the GAMA argues the proposed part 38 fuel efficiency standards would apply to FAA type certificated part 23 airplanes at the maximum allowable MTOW of 19,000 lbs. The GAMA suggested two alternative approaches to address this potential unit conversion issue in § 38.1 MTOM references: (1) use 8,619 kg in all

instances for MTOM threshold for propeller-driven airplanes instead of 8,618 kg; or (2) list both the applicable MTOM (mass) of 8,618 kg and MTOW (weight) 19,000 lbs.

Response: The FAA acknowledges that conversion from 8,618 kg to lbs equates to a weight that is approximately 0.5 lbs less than the 19,000 lbs threshold of other FAA regulations. However, when applying the conversion in reverse, going from 19,000 lbs to kg, the result is 0.25 kg greater than 8,618 kg. This difference of less than 1 lb or 1 kg is extremely small; it is unlikely that an airplane would fall within this conversion difference. Importantly, differences less than 1 lb or 1 kg would not be reflected in either a TCDS or an airplane flight manual. Additionally, the use of kilograms as the applicability threshold is consistent with the EPA standards. For these reasons, the FAA finalizes the threshold as proposed in § 38.1(a)(3)(i).

Comments: The MARPA requested that the FAA clarify that part 38 does not apply to parts manufactured by holders of a Parts Manufacturer Approval (PMA). In particular, the MARPA asked that the FAA include text in the preamble to the final rule stating that the rule applies only to the design and approval of type certificated products. In addition, the MARPA wanted this text to also state that the proposed rule does not apply to Parts Manufacturer Approval (PMA) manufacturers of modification and replacement parts under part 21 subpart K.

Response: The FAA disagrees with adding the suggested text to the preamble. The applicability section does not apply to parts manufactured by holders of a PMA. Because these parts have the same fit, form, and function of the parts they replace they are not considered a change in type design.

Comment: One individual thought that this rule would benefit those who use private airplanes for travel, implicitly indicating that those types of planes would not need to comply with part 38.

Response: The FAA disagrees as the applicability of this rule includes all airplanes that meet the applicability requirements regardless of who is using the airplane or whether they are privately owned. The type of airplanes described by the commenter are not necessarily exempted from the rule.

E. Exceptions to Applicability (§ 38.1)

In the NPRM, the FAA proposed several exclusions to the applicability of part 38. Part 38 would not apply to airplanes with lesser MTOMs than those

specified in § 38.1(a). Part 38 also would exclude airplanes that are designed for specialized operations (including the presence of unique design features to carry out those operations). The NPRM also would exclude amphibious airplanes, airplanes that have no pressurized areas, airplanes designed for firefighting, and airplanes powered by reciprocating aircraft engines.

1. Discussion of the Final Rule

In § 38.1(c), the FAA is adopting the same exclusions to part 38 that were adopted by the EPA and ICAO. The section is remaining as proposed, except for one minor non-substantive change in § 38.1(c)(4) where the FAA switched the EPA and FAA references so that the FAA is identified first as the agency is issuing this rule.

As finalized, part 38 does not apply to airplanes with lower MTOMs than those specified in § 38.1(a) and § 38.1(c)(1) and (2)). The rule also excludes airplanes that are initially designed, or modified and used, for specialized operations (including the presence of unique design features to carry out those operations) from part 38, subject to a determination that a design for specialized operation is detrimental to fuel efficiency. The FAA and the EPA would make this determination at the time an airplane is presented for certification. Examples of such airplanes could include specialized cargo features, specialized missions, or crop dusting (§ 38.1(c)(4)). The rule excludes from part 38 the following: amphibious airplanes (as defined in § 38.3); airplanes that have no pressurized areas (described as having zero reference geometric factor (RGF)); airplanes designed for, or modified and used for, firefighting; and airplanes powered by reciprocating aircraft engines (§ 38.1(c)(3), (5), (6), and (7)).

2. Public Comments and FAA Response

Comments: Commenters, including Boeing and AIA (echoed by GE¹³), requested that the FAA clarify and revise the regulatory text to explicitly state that the rule only applies to civil airplanes and not military airplanes. The AIA specifically requested clarification that part 38 did not apply to state airplanes, such as those used by military, customs, and police services,

¹³ GE specifically incorporated by reference Boeing's substantive, non-technical comments on the NPRM, including comments on the applicability to military aircraft and other requested changes for alignment with EPA and ICAO standards. GE also specifically incorporated by reference AIA's substantive comments on the proposed rule, including comments on the inapplicability of the rule to state aircraft and modifications to an in-service aircraft.

or other types of airplanes, such as rotorcraft or piston-engine airplanes. Boeing requested that the FAA clarify the language in § 38.1(a) so that the regulation explicitly states that part 38 only applied to civil airplanes as defined in 14 CFR 1.1.

Boeing further requested a change in § 38.1(a) from original type certification to original civil certification. Boeing believed this change and other consistency changes would remove any ambiguity and clarify that only airplanes seeking civil certification are subject to the rule. GE supported Boeing and AIA comments on this issue.

Response: The FAA disagrees with the request to explicitly revise the regulatory text to state that the rule only applies to civil airplanes and not military airplanes. This rule addresses the certification of fuel efficiency for subsonic, civil airplanes.¹⁴ As defined in 14 CFR 1.1, civil aircraft are aircraft other than public aircraft. Public aircraft is an operational status under the statute, not a certification status, since any airplane operated by a valid government entity could be a public aircraft depending on its use. 49 U.S.C. 40102(a)(41), 40125. Because the FAA cannot predict whether a type certificated airplane may be used for a public aircraft operation, and the status of that airplane may change from civil to public and back on a flight-by-flight basis, the FAA finds that this distinction is not appropriate for purposes of this rule.

Further, the FAA disagrees with Boeing's suggested change to original civil certification. The FAA does not reference its airworthiness certificates as "civil certificates." The FAA uses terminology such as "original type certificates," consistent with part 21.

Thus, the FAA declines to modify § 38.1 as suggested by commenters.

Comments: Commenters also suggested the FAA clarify that part 38 does not apply to airplanes that are initially certificated as civil airplanes during the production process but immediately used for military operations. Both AIA and Boeing explicitly requested that the FAA add these types of airplanes to the list of airplanes not covered by the rule in § 38.1(c). Boeing also requested corresponding changes to the draft Advisory Circular. These commenters indicated that these changes are consistent with the ICAO standards. In particular, they referenced the ICAO Environmental Technical Manual

(ETM)¹⁵ and its inclusion of these types of airplanes in a list of examples of specialized operational requirements. Because the FAA had included language in the NPRM to propose the same exclusions adopted by ICAO, Boeing stated the FAA should include language excluding these types of airplanes from coverage under part 38. Boeing stated the exception would be consistent with the examples for these airplanes in the ICAO guidelines (the ETM). Boeing also indicated that this exception would be consistent with past EPA and Department of Defense (DOD) practice, citing to the EPA's 2012 Final Rule adopting new aircraft engine emissions standards for nitrogen oxides.

Response: Commenters indicated that to be consistent with the ICAO standards, the FAA needs to exclude from part 38 a civil-certificated airplane immediately converted to military use. The FAA disagrees with the underlying premise that part 38 does not apply to civil certificated airplanes immediately converted to military use. The FAA regulations are consistent with ICAO Annex 16 Volume III standards, which contain no such exemption. The ICAO language suggesting the exception of military airplanes from CO₂ applicability is in ICAO guidance (*i.e.*, the ETM guidance document to Annex 16 Volume III), not in the ICAO standards (*i.e.*, Annex 16 Volume III).¹⁶ The FAA is not obligated to include in its standards any exception suggested in ICAO guidance that is not in the ICAO standard.

The FAA has no authority over military airplanes involved in public aircraft operations, and its regulations do not apply to airplanes produced for the armed services. The FAA certification regulations apply only to airplanes that seek civil certification in the United States. When an airplane is produced, the FAA issues an airworthiness certificate for that airplane if it conforms to the type design and complies with all applicable civil regulations. FAA regulations do not consider intended use or conversion involved in airplane certification—either the airplane complies with all regulatory requirements and is eligible for a civil airworthiness certificate, or it does not.

¹⁵ Volume III—Procedures for the CO₂ Emissions Certification of Airplanes, § 2.1.3.

¹⁶ The FAA inadvertently included guidance from ICAO's Environmental Technical Manual in the draft AC38 that was included in the docket for review with the NPRM. The exception has never been included in the part 38 rule text, and for the reasons discussed it has been removed from the final AC38.

A manufacturer may produce airplanes and parts for the military without involving the FAA. If an applicant requests civil certification from the FAA, the applicant must satisfy all applicable regulations for that airplane regardless of the potential for that airplane's use for military operations.

In the United States, the FAA has no statutory authority over military airplanes involved in public aircraft operations. Part 38 does not apply to these airplanes; accordingly, these airplanes cannot be exempted or excluded from something that does not apply in the first place. For these reasons, the FAA does not see the need to modify § 38.1(c) in this respect.

F. Definitions (§ 38.3)

In the NPRM, the FAA proposed several definitions for part 38. These definitions would be specific to fuel efficiency certification. The proposed definitions included: amphibious airplane; ICAO Annex 16, Volume III; maximum takeoff mass (MTOM); performance model; reference geometric factor (RGF); specific air range (SAR); subsonic; and type certificated maximum passenger seating capacity.

1. Discussion of the Final Rule

The rule includes a definitions section as § 38.3. The section is adopted, as proposed, except this rule makes modifications to the definition of maximum takeoff mass (MTOM) based on comments received.

2. Public Comments and FAA Response

Comments: Some commenters suggest the FAA include additional definitions, such as "subsequent version" and "modified type design."

Response: See responses to these comments that are discussed in section IV.D.

Comments: The FAA received several comments on the definition of Maximum takeoff mass (MTOM) in § 38.3. Specifically, Airbus commented that the definition of MTOM should be modified by replacing "maximum allowable" with "highest of all certified" takeoff masses. Airbus stated that the proposed definition could be misinterpreted and suggested clarifying that the MTOM represents the highest of all of the certified takeoff masses in the Type Certificate Data Sheet (TCDS). Airbus also suggested replacing "approved certification basis" with "Type Certificate Data Sheet" since the approved certification basis of a type design generally represents the set of applicable requirements to the type

¹⁴ 87 FR at 36082.

design and it would be more exact to refer to the TCDS.

Response: The FAA does not agree that “highest of all certified” should replace “maximum allowable” in the definition of MTOM. The MTOM is intended to mean the maximum takeoff mass an airplane type design is certified to and recorded in the TCDS. As mentioned by an individual commenter, the FAA agrees that the TCDS may contain several maximum takeoff masses for different variants of the same airplane type design, and the MTOM is the highest of these maximum takeoff masses. The comments reflected confusion around which maximum mass was meant—maximum structural, maximum takeoff for an airplane, or the maximum mass of several variants of similar design. The FAA does recognize that the definition as proposed was not clear on this point and is changing “maximum allowable takeoff mass” to “maximum certified takeoff mass,” which clarifies reference to certified MTOM values in the TCDS. The FAA also notes that the use of “maximum certified takeoff weight” (similar to maximum certified takeoff mass) is used in other parts of title 14 CFR, including parts 21, 25, and 36.

Regarding the reference in the proposal to the “approved certification basis” and the requests to replace this phrase in the MTOM definition with “TCDS,” the FAA agrees that the TCDS is the appropriate document to reference in determining the maximum takeoff weight for FAA-certified variants of the base model. However, the FAA decided to remove “approved certification basis” from the regulatory text, and not replace it with “TCDS,” because the change to “maximum certified takeoff mass,” earlier in the definition addresses these concerns. Applicants may propose the use of the highest weight of an airplane type design to represent lower-weight variants. This allowance provides flexibility to applicants who may not be interested in certifying an individual FEM value for each lower weight variant. Such proposals will be considered on a case-by-case basis for FAA approval as provided in § 38.23.

Comment: Boeing commented that the FAA should revise its description of the MTOM definition to clarify that MTOM is not an international standard term for airplane weight expressed in kilograms. Boeing indicated that its expression in kilograms is not integral to its meaning. Boeing requested that the FAA revise its description to state that the MTOM is the highest of all takeoff masses for the type design configuration.

Similarly, an individual commented that although MTOM needs to be

expressed in kilograms for use in showing compliance with the proposed requirements, MTOM is not an international standard term for airplane weight expressed in kilograms. In addition, the commenter noted that MTOM is the highest maximum takeoff mass specified for the airplane type design as stated in the airplane TCDS, and that the TCDS may contain several maximum takeoff masses (identified as maximum takeoff weights in the TCDS) for different weight variants for the same airplane type design. The commenter concluded by stating that the MTOM is the highest of these maximum takeoff masses.

Response: The FAA acknowledges that in the NPRM preamble the FAA described MTOM as the international standard term of airplane weight expressed in kilograms. The FAA recognizes that this statement is incorrect as MTOM is not an international standard term for airplane weight.

The FAA made minor revisions for clarification and moved the reference to kilograms to be more closely associated with the relevant terms.

As a result, the FAA has modified the definition of MTOM in this final rule to be:

The maximum certified takeoff mass, expressed in kilograms, for an airplane type design

Comment: A commenter asked that the definition of MTOM include the phrase “for the purposes of complying with the requirements of this part.”

Response: The FAA notes that § 38.3 already begins with the phrase, “For the purpose of showing compliance with this part, the following terms have the specified meanings:.” Based on that, the FAA has not changed the definition as suggested by the commenter.

Comment: Airbus provided a comment on the definition of “Performance model” stating that in the phrase “using corrected flight test data that can be used to determine the specific air range values,” the word “corrected” should be removed since test data in test conditions could also be used to validate a performance model.

Response: The FAA disagrees with this change as it would cause a substantive difference between the FAA and the EPA and ICAO standards, both of which include the term “corrected flight test data” in the definition (See, e.g., 40 CFR 1030.105). A substantive difference would change the meaning, intent, or level of a particular requirement.

G. Compatibility With Airworthiness Requirements (§ 38.4)

As proposed, this section addressed compatibility between environmental and airworthiness standards. The NPRM intended to prohibit the sequencing of certification tests for an airplane that has not met the applicability airworthiness requirements. This requirement would ensure that no airworthiness requirements are compromised during the fuel efficiency certification. In addition, the FAA proposed to require that all the procedures used to conduct the flights to demonstrate fuel efficiency compliance be conducted in compliance with all airworthiness regulations that apply to the airplane.

1. Discussion of the Final Rule

The FAA received one comment on § 38.4 regarding the sequencing of certification tests. The FAA did not make any changes to the section based on the comment and is adopting the section as proposed.

2. Public Comments and FAA Response

Comment: Gulfstream asked if an applicant, when developing an aeropropulsion model, could substantiate the score by conducting some of the testing (on a conforming test article) before 100% of airworthiness certification is complete.

Response: The FAA recognizes that Gulfstream’s comment was in response to a sentence in the NPRM preamble noting that § 38.4 is intended to prohibit the sequencing of certification tests for an airplane that has not met the applicable airworthiness requirements. In response to Gulfstream’s question, the FAA clarifies that testing could be done on a type design conforming test article before 100% of the airworthiness certification is complete. The airplane configuration conformed for fuel efficiency testing purposes must represent the configuration sufficiently such that the FEM is representative of the final type design. The FAA must approve configuration(s) not completely conforming to the type design prior to testing. The FAA did not revise the regulatory text based on this comment.

H. Exemptions (§ 38.5)

In the NPRM, the FAA proposed a process for exemptions. The NPRM proposed that a petitioner submit petitions for exemption from any requirement in part 38 in accordance with 14 CFR part 11. The proposal also noted that the FAA would consult with the EPA on any request for exemption from the regulations of part 38. This proposed process is the same process

the FAA follows when it considers petitions for exemption from the engine emissions standards promulgated by the EPA under 40 CFR part 87 and by the FAA in 14 CFR part 34.

1. Discussion of the Final Rule

The FAA is adopting § 38.5 as proposed. In accordance with 42 U.S.C. 7572, 49 CFR 1.83(a)(6) and (c), and 49 U.S.C. 44701(f), the FAA may issue exemptions from its regulations when such exemption would be in the public interest. As adopted, § 38.5 continues to provide for submittal of petitions for exemption from any requirement in part 38 in accordance with 14 CFR part 11. The FAA is adopting § 38.5 as proposed.

2. Public Comments and FAA Response

Comments: Some commenters, including AIA, A4A, Boeing, NBAA, and Airbus, expressed overall support for the FAA's approach to addressing exemption requests from part 38. In particular, Boeing supported the use of the public interest standard under 49 U.S.C. 44701 in considering exemptions. Several commenters requested clarity on the FAA process for exemptions in § 38.5.

Response: The FAA will follow its standard process for petitions for exemption that are outlined in 14 CFR part 11. Section 11.15 of these regulations defines a petition for exemption and §§ 11.61 through 11.103 contain the FAA's regulatory process for exemptions. Part of what must be included in a petition for exemption is an explanation of why the proposed action will be in the public interest (14 CFR 11.71). Section 38.5 adds a requirement to this process as it provides that the FAA consult with the EPA on each exemption petition before taking action. This process is the same as that followed when the FAA considers petitions for exemption from the engine emissions standards promulgated by the EPA under 40 CFR part 87 and by the FAA in 14 CFR part 34.

Comment: Airbus requested that the FAA provide information on the number of exemptions that could be granted and whether the FAA would follow the ICAO recommendations in granting exemptions.

Response: How the FAA will process future exemptions under part 11 and the possible number of exemptions the FAA could issue is outside the scope of this rulemaking. Although ICAO provides some guidance on exemptions that member countries could consider, the FAA processes each request for exemption on a case-by-case basis.

I. Incorporation by Reference (§ 38.7)

In the NPRM, the FAA noted that it was reserving § 38.7 for materials to be incorporated by reference into part 38. As part of the final rule development, FAA assessed the references to external documents throughout the proposed rule and is incorporating by reference ICAO Doc 7488/3, *Manual of the ICAO Standard Atmosphere (extended to 80 kilometres (262 500 feet))*, 1993 (Manual) in § 38.7. The Manual was identified in the part 38 Appendix and the FAA did not receive any comments on the Manual. Specifically, this Manual is referenced in sections A38.2.1.3.1, A38.5.2.2.1.9, and A38.5.2.2.1.10 of Appendix A to part 38. In these sections, the applicant must use this Manual to establish certain reference specifications when determining SAR.

The OFR has regulations concerning incorporation by reference (1 CFR part 51). These regulations require that, for a final rule, agencies must discuss in the preamble the way in which the materials that the agency incorporated by reference are reasonably available to interested persons, and how interested parties can obtain the materials. In addition, in accordance with 1 CFR 51.5(b), the agency must summarize the material in the preamble of the final rule.

In accordance with the OFR's requirements, the Manual provides the standard values of atmospheric parameters, the values of constants and coefficients, and the underlying equations used in the calculation of the atmospheric parameters. The Manual is intended for use in calculations in the design of airplanes, in presenting test results of airplanes and their components under identical conditions, and in facilitating standardization in the development and calibration of instruments.

Interested persons can purchase this Manual from the ICAO Store at 999 Robert-Bourassa Boulevard Montréal (Quebec) Canada H3C 5H7, (www.store.icao.int).

J. Relationship to Other Regulations (§ 38.9)

Section 38.9 in the proposed rule described the authority of the EPA and the FAA under the Clean Air Act to set and implement standards for aircraft engine emissions. In proposed § 38.9, if the EPA changed any requirement in 40 CFR part 1030 that corresponded with a regulation in part 38, applicants could request a waiver for provisions as they appear in part 38 to comply with the changes; proposed § 38.9 also described

the circumstances under which a waiver may be granted.

This proposed section also provided that, unless otherwise specified in this part, all terminology and abbreviations in part 38, that are defined in 40 CFR part 1030, have the same meaning as specified in part 1030.

The FAA did not receive comments on this section. However, the FAA did make some corrections to the text, including fixing a typographical error and an incorrect reference to the DOT delegations of authority to the FAA. Other than these corrections, the FAA is adopting this section as proposed.

K. Fuel Efficiency Metric (§ 38.11)

The NPRM proposed that the fuel efficiency of an airplane be determined by the amount of fuel it uses to travel a certain distance under prescribed conditions. This measure was proposed as the fuel efficiency metric (FEM). As proposed, for each airplane subject to part 38 (including an airplane subject to the change criteria of § 38.19), § 38.11 would require the calculation of an FEM value using an equation identical to the one adopted by the EPA in 40 CFR 1030.20.

1. Discussion of the Final Rule

The FAA is adopting § 38.11 as proposed. This section describes the FEM of an airplane. The FEM value is calculated using an equation identical to the one adopted by the EPA. The two primary components of the FEM are the SAR (provided in § 38.13) and the RGF (provided in § 38.15). As described in § 38.11, the FEM is ultimately calculated by dividing the average SAR values by RGF in a universal equation to denote the fuel efficiency of any airplane in a manner that is transport capability neutral.

2. Public Comments and FAA Response

Comment: Gulfstream commented that the NPRM preamble description for § 38.11 was confusing and highly simplified when it stated that dividing SAR by RGF results in a universal equation to denote the fuel efficiency of any airplane regardless of size.

Response: The FAA notes that the preamble is not meant to reflect every detail of the rule, but rather summarizes its contents and elaborates as necessary. The statement was referring to the fuel efficiency metric equation, provided in § 38.11, which is $(1/\text{SAR})_{\text{average}}$ divided by $\text{RGF}^{0.24}$. In describing it as a universal equation, the FAA was referring to the fact that these parameters also comprise the metric in ICAO's international Aeroplane CO₂ Emissions standard.

Comment: An individual commented that the FEM seems to be defined upside down because the higher the fuel efficiency value gets, the worse the airplane is, efficiency-wise.

Response: The term “Fuel Efficiency Metric” (FEM), as used in this rule, is not a measure of airplane fuel efficiency, as commonly understood. This rule uses a newly defined term, FEM, that represents a correlation to the level of GHG emissions produced by the airplane.

The ICAO designed the FEM system (the FEM metric plotted against MTOM) similarly to other ICAO environmental standards, where the FEM of an airplane must be below a limit line to pass the standard. In order to achieve this result, the parameter SAR was inversed (*i.e.*, 1/SAR).

L. Specific Air Range (§ 38.13)

Section 38.13 of the NPRM proposed the requirements for determining SAR, one of the two primary components of the FEM.

1. Discussion of the Final Rule

As adopted, Section 38.13 describes the SAR. The SAR is an aeronautical parameter used in the aviation industry to represent the distance an airplane can travel per unit of fuel consumed. In part 38 it is used to represent the instantaneous fuel efficiency of an airplane at any point during stable cruise flight. The FAA made one minor revision to § 38.13(a)(2)(ii) by replacing “made” with “submitted” to be consistent with the FAA’s intent. The FAA made a second minor revision to add the word “or” after § 38.13(a)(1) to indicate the requirements more clearly. Otherwise, the FAA is adopting this section as proposed.

2. Public Comments and FAA Response

Comment: Boeing suggested that § 38.13(b), as proposed, could be overbroad and subject to misinterpretation as it could limit SAR calculations until the performance model is approved by the FAA. Boeing requested that the FAA change “are made” to “are submitted.”

Response: The FAA agrees that this requirement could be read to mean applicants may not make SAR calculations, whether for compliance or not, until the performance model is approved by the FAA. That was not the intent of this requirement. In the final regulatory text, the word “made” is changed to “submitted.”

Comment: Boeing commented that the SAR should be multiplied by the airplane’s instantaneous weight in order to be used as a measurement of fuel

efficiency. Boeing suggested clarifying that in part 38, the term “efficiency” is used to represent the instantaneous fuel efficiency of an airplane at any point during stable cruise flight. Other individual commenters agreed with Boeing’s assertion that SAR alone does not measure the fuel efficiency of an airplane.

Response: The FAA recognizes that the parameter SAR does not “measure” the instantaneous fuel efficiency. As stated above, SAR is the distance an airplane can travel per unit of fuel consumed to represent instantaneous fuel efficiency. Inherently, the determination of instantaneous SAR already includes the instantaneous weight of the airplane (*i.e.*, structural efficiency in context of this rule), as well as the airplane aerodynamic and propulsive efficiencies of the airplane. The FAA agrees that, in this part, SAR is used to represent the instantaneous fuel efficiency of an airplane at any point during stable cruise flight.

Comment: Gulfstream requested clarification of the FAA’s expectations for substantiation of the performance model and allowances for weight increases.

Response: Although models may be built with first principles analysis or wind tunnel data, the model used to show compliance must be validated by flight test data and approved by the FAA. The FAA must also approve any allowances regarding models. See section 38.13. The AC38 contains additional related guidance.

Comment: An individual commenter questioned the need for the statement to exclude auxiliary power units (APU) from the 1/SAR calculation in § 38.13(c), stating that they would not normally need to be included. The commenter noted that if there was ever a design where they did need to be included for some reason, this requirement would preclude that. Another commenter said that APU usage for traditional airplanes should be included because the goal is to reduce the consumption of hydrocarbons rather than potentially shifting the location where hydrocarbons are burned from a place where they are included to one where they are not.

Response: Section 38.13 specifically excludes APUs from the SAR calculation. The EPA’s standard in 40 CFR 1030.23 also contains this exclusion and this is a key component of the standards. To comply with 42 U.S.C. 7572 and maintain consistency with EPA’s standards in 40 CFR part 1030, the FAA is adopting this paragraph as proposed.

M. Reference Geometric Factor (§ 38.15)

Section 38.15 of the NPRM proposed the requirements for determining RGF, one of the two primary components of the FEM.

1. Discussion of the Final Rule

As adopted, § 38.15 describes the RGF. The RGF is a representation of airplane fuselage size based on the floor area of pressurized space in an airplane and is flexible enough to account for single or multi-deck airplanes. This rule adopts changes from “cockpit” to “flight deck” to provide gender-neutral language without changing the meaning or intent. Other than this change, the FAA is adopting this section as proposed.

2. Public Comments and FAA Response

Comments: Some commenters, including A4A and Boeing, requested clarifications on FAA’s descriptions of the RGF. Specifically, they requested that the preamble state that the RGF is a representation of airplane fuselage size based on the floor area of pressurized space in an airplane and is flexible enough to account for single or multi-deck airplanes. They further stated that dividing SAR by RGF results in a universal equation to denote the fuel efficiency of any airplane in a manner that is transport capability neutral (which is the FEM). Boeing stated that this change was needed because RGF was not developed to account for productivity and load carrying capability, noting that RGF was included to achieve the aim of having a transport-capability-neutral metric.

Response: The FAA agrees with A4A and Boeing’s characterization of RGF, specifically its purpose to create a transport capability neutral FEM, and the FAA believes the regulatory text is consistent with this description. As a result, FAA has determined that no changes to § 38.15 are necessary based on this comment.

Comment: An individual commenter questioned the appropriateness of RGF. The commenter proposed an example to show that a poorly designed airplane could have a similar FEM value as a better-designed airplane. The commenter also questioned the value of the RGF concept when passengers or payload transported over a given distance, per unit of energy input could be considered instead.

Response: The FAA disagrees. A specific goal of the standards are to avoid unintentionally incentivizing airplane manufacturers to design airplanes for specific operational objectives, such as payload-carrying

capability or mission range. The RGF is not intended to account for an airplane's transport capabilities (e.g., its productivity or payload-carrying capability). Instead, the use of RGF in this regulation creates a transport capability neutral fuel efficiency metric. The FAA asserts that RGF is appropriate.

The FEM system is designed to account for aerodynamic, structural (i.e., airplane weight), and propulsive efficiencies using its SAR parameter, and utilizes RGF to normalize those efficiencies across a broad range of MTOMs. If two airplanes have the same efficiencies in these three categories as well as in RGF, as described in the commenter's example, then the FEM will be the same—regardless of whether the interior layout or sub-weight components of MTOM result in a poor design with respect to a particular operational purpose.

N. Fuel Efficiency Regulatory Limits (§ 38.17)

As proposed, § 38.17 incorporated, as fuel efficiency limits, the emission standards adopted by the EPA in 40 CFR 1030.30. Airplanes subject to part 38 would be required to demonstrate that the FEM value does not exceed the fuel efficiency limits in § 38.17. Using the applicable provision in § 38.1, the NPRM proposed calculating the fuel efficiency limit using the airplane's MTOM and the equations listed in the last column of the table in § 38.17(b).

The FAA did not receive comments on this section and is adopting it as proposed.

O. Change Criteria (§ 38.19)

As proposed, this section would apply the fuel efficiency requirement at the time certain modifications were made. The NPRM would adopt the EPA airplane change criteria of 40 CFR 1030.35. The change criteria proposed in § 38.19 described the modifications affecting compliance. The requirements differ depending on whether or not the airplane had previously demonstrated compliance with part 38.

1. Discussion of the Final Rule

Section 38.19 provides the change criteria for modified airplanes. Section 38.19 adopts the EPA airplane change criteria of 40 CFR 1030.35.

As discussed in section IV.D. of this preamble, the third occasion when part 38 applies is at the time certain modifications are made to the airplane. Airplanes routinely have modifications incorporated into their designs. A modification may require demonstration of compliance to part 38, regardless of

whether the airplane was required to previously demonstrate compliance with part 38.

The change criteria in § 38.19 describe the modifications which require compliance with part 38. The requirements differ depending on whether an airplane demonstrated compliance with part 38 before a modification is made, or whether an airplane was type certificated before January 1, 2023, and had not previously demonstrated compliance to this rule. The change criteria in § 38.19(a) indicates that a compliance demonstration to this new rule is required if a modification to an airplane, that has been shown to comply with § 38.17, will increase the MTOM of the airplane as written in § 38.19(a)(1) or increases the FEM value above the thresholds provided in § 38.19(a)(2)(i) through (iii). Where an airplane has been shown to comply with § 38.17, for a modification that does not increase either the MTOM or the FEM value, then under section § 38.19(b) the airplane may retain the same FEM value as prior to modification. The last piece of the change criteria in § 38.19(c) provides that an airplane, which meets the applicability provisions of § 38.1(a)(4) or (5) on or after January 1, 2023, and before January 1, 2028, must demonstrate compliance if the incorporated modifications exceed 1.5% when comparing its FEM before and after the modifications.

The FAA received several comments on this section. Some of these comments were directly related to § 38.1 because of the relationship between the regulatory text of §§ 38.1 and 38.19. As such, the FAA responded to some of the § 38.19 comments in the related applicability responses (see IV.D. General Applicability). As a result of FAA responses to those comments in the general applicability discussion, FAA made changes to § 38.19(b) and (c). As a result of other comments, the FAA made minor clarification changes to § 38.19(a)(2)(i) and (ii) and (b). Other than these changes, the FAA adopts the section as proposed.

The FAA recognized that the change criteria as proposed in the NPRM may have been difficult to understand because it described the change criteria thresholds as “values” that could be confused with fuel efficiency metric “values” described in § 38.11. The FAA made minor edits to the text in § 38.19(a) to remove the potential for confusion by properly describing the change criteria as a threshold whereby changes in fuel efficiency metric values are compared to the thresholds in percentages.

2. Public Comments and FAA Response

Comment: Several commenters, including Embraer, Boeing, AIA, and Airbus, commented on § 38.19(b) that the text “this paragraph (b)” should say “paragraph (a) of this section.”

Response: The FAA agrees that this was a typographical error and has corrected the text.

Comment: Airbus recommended that the non-cumulative (non-tracking) nature of changes that meet the change criteria, a core part of the change criteria developed by ICAO, should be mentioned in either part 38 or AC38.

Response: The FAA disagrees. The FAA recognizes that the ICAO standard and the EPA rule do not require cumulative tracking of airplane modifications to a type design. In kind, the FAA also does not have such a requirement. Since there is no requirement to track cumulative modifications, the FAA does not see a need to include any explanation of modification tracking in either part 38 or the AC38.

Comment: Boeing asked to clarify § 38.19(a)(2)(i) and (ii) by specifying the MTOM starting point associated with the percentage starting point in these two change criteria.

Response: The FAA agrees these edits may help to clarify the requirement. The FAA has added the phrases “for an airplane with a MTOM of 5,700 kg” to clarify the 1.35 percent in § 38.19(a)(2)(i) and “for an airplane with an MTOM of 60,000 kg” to clarify the 0.75 percent in § 38.19(a)(2)(ii).

Comment: Gulfstream requested that the FAA provide clarification for documentation expectations in § 38.19(c). Gulfstream noted that it is not clear how it is determined and what the FAA expectation will be to document that a modification does not increase the FEM by more than 1.5%.

Response: For context, § 38.19(c) requires an airplane that meets the criteria of § 38.1(a)(4) and (5) on or after January 1, 2023, and before January 1, 2028, to demonstrate compliance with § 38.17 if it incorporates any modification that increases the FEM value of the airplane by more than 1.5% prior to modification.

Regarding the portion of Gulfstream's comment on documentation expectations, the FAA will determine whether part 38 applies to a covered airplane according to the criteria in § 38.19(c) and the supporting documentation provided by the applicant. This determination is part of the type design change certification process in § 21.93(d) and FAA will decide documentation expectations on a

case-by-case basis depending on the complexity of the type design change.

Comment: Gulfstream asked how a change in the FEM value is determined.

Response: The requirements in part 38 and its appendix provide the detailed information required to determine a fuel efficiency metric value for a type design, such as corrections, tolerances, and confidence intervals. The AC38 provides additional detailed guidance and worked examples on how applicants can evaluate the FEM value for an airplane.

Comment: An individual commented that the magnitude of change in the FEM value caused by the addition of a satellite antenna could be lower than in the example provided in that discussion.

Response: The FAA acknowledges that FEM value changes due to modifications to airplanes could vary significantly. As provided in § 38.19, the FEM values can increase or decrease when there are modifications to an airplane that impact aerodynamics.

The NPRM discussion for § 38.19 intended to focus on how the change criteria thresholds work, rather than the specific examples themselves. This comment does not require changes to the regulatory text.

P. FAA Approval Before Compliance Testing (§ 38.21)

As proposed, § 38.21 would require FAA approval of all procedures, weights, configurations, and other information needed to calculate the FEM value of an airplane. As described in the NPRM, the FAA would not apply this section to data an applicant submits for validation following fuel efficiency certification by another authority.

1. Discussion of the Final Rule

As adopted, § 38.21 requires FAA approval of all information needed to calculate the FEM value of an airplane. The FAA approvals are necessary and establish the airplane configuration and fuel efficiency certification procedures. These procedures remain unchanged before fuel efficiency compliance tests are conducted. This section does not apply to data submitted for validation following fuel efficiency certification by another authority. The FAA received several comments on proposed § 38.21. The FAA adopts § 38.21 as proposed.

2. Public Comments and FAA Response

Comment: The GAMA requested that the FAA add the phrase “documented in compliance demonstration plans” before “approved by the FAA” to § 38.21.

Response: The FAA finds the proposed change to be too prescriptive. Section 38.21 requires FAA approval of certain items prior to compliance testing, including procedures, weights, configurations, and other information. These items are used to establish the fuel efficiency level. Compliance demonstration plans may be one way of providing this information to the FAA. However, the FAA intends to preserve the ability for applicants to use other mechanisms to provide the required information to the FAA. The GAMA’s proposed change would remove this flexibility.

Q. Manual Information and Limitations (§ 38.23)

As proposed, § 38.23 would require placement of the FEM value of the airplane, along with other part 38 compliance information, in an FAA-approved section of the flight manual of the airplane. Inclusion of this information in the approved airplane flight manual would provide owners, operators, and flight crew with information regarding the airplane’s compliance with part 38. The FAA proposed that if a weight lower than the MTOM was used for fuel efficiency certification, then that lower weight becomes an operating limitation for that airplane and would be included in the operating limitations section of the flight manual. As provided in the NPRM, operators could not exceed the weight at which compliance with part 38 was demonstrated, even if that weight was lower than the MTOM for the airplane under other airworthiness requirements.

1. Discussion of the Final Rule

The FAA made one change to this section in response to comments to specify that the manual include the fuel efficiency level as established in part 38. Other than the change to § 38.23(a)(1), the FAA adopts the regulation as proposed.

2. Public Comments and FAA Response

Comment: Boeing suggested clarifying the language in § 38.23(a)(1) to refer to compliance, as required by the part, rather than during certification. Boeing indicated that the proposed text could give rise to potential ambiguity with respect to an in-production airplane that complies with the fuel efficiency requirement in part 38, and compliance to part 38 need not be shown during type certification. Further, Boeing remarked that there is no reason that the compliance demonstration itself needs to be done during type certification and the FAA’s regulatory language should be

sufficiently flexible to accommodate such an approach.

Response: The FAA concurs with the change proposed by Boeing and has replaced “during type certification” with “as required by this part” in § 38.23(a). The use of “as required by this part” more specifically refers to the part 38 requirements rather than the type certification process.

Comment: Airbus suggested removing the requirement to publish certified fuel efficiency data in the flight manual by deleting §§ 38.23 and 21.5(b)(3). Airbus indicates that the adoption of these provisions would create de-harmonization between certification authorities. Airbus instead suggests relying on the ICAO CO₂ databank maintained by the FAA as well as through the EASA CO₂ databank. Using the same justification, Airbus also requested that the FAA remove the proposed flight manual requirements from §§ 121.141(b) and 125.75.

Airbus was also concerned that if the certification applicant chooses to certify several MTOMs against the new part 38, several flight manual supplements would have to be created and maintained for the same airplane model.

Response: The FAA disagrees with removing the flight manual publication requirement. Although most information may be available through the ICAO CO₂ database¹⁷ or another certification authority-maintained database, these databases are either outside the FAA’s control or potentially incomplete, because manufacturers are not required to submit information to the database. For these reasons, the databanks may not provide a complete set of information and may not contain information for a particular airplane. The inclusion of fuel efficiency levels and MTOM in the flight manual associated with a serial number specific airplane allows anyone, including an authority, to determine the compliance state of an airplane.

For these reasons, the FAA is retaining these requirements.

Comment: Gulfstream asked if the industry could expect to see airports imposing fees or restrictions based on fuel efficiency, similar to noise, that would motivate an applicant to certify an airplane at a lower MTOM. Gulfstream recommended clarifying the potential for any benefit with artificially limiting the MTOM to a lower value than the design specification.

¹⁷ The FAA hosts but does not control the contents of the ICAO Airplane CO₂ Certification Database located at: www.faa.gov/headquarters/offices/apl/ae/icao-airplane-co2-certification-database.

Response: The FAA cannot speculate as to whether third parties, such as airports, would impose fees or restrictions on airplanes based on these fuel efficiency values.

R. Appendix A to Part 38

As proposed, Appendix A provided the technical detail needed to determine the FEM value of an airplane required to demonstrate compliance with part 38. It also detailed the process and procedures an applicant needed to use when measuring an airplane for fuel efficiency. The proposal also described the data the applicant would submit to the FAA.

1. Discussion of the Final Rule

As adopted, Appendix A to part 38 provides the technical, certification-specific details an applicant needs to determine the FEM value of an airplane and demonstrate compliance with part 38. The primary sources of the information contained in the appendix are Sections 2.5 and 2.6 of ICAO Annex 16, Volume III, as well as appendices 1 and 2 to that volume. These sources of information were not included in the EPA rule directly but were incorporated by reference. In coordination with the EPA, the FAA decided it was important to include such certification-related details in part 38 given the FAA's responsibility to enforce the EPA rule within the FAA airplane certification framework. As a result, in this rule, the FAA does not incorporate this Annex information by reference but includes all the requirements from Annex 16 Volume III using current United States certification terminology, format, and references.

Appendix A to part 38 details the processes and procedures to be used when measuring an airplane for fuel efficiency. To comply with part 38, a certification applicant would need to determine the core parameters of the FEM, specifically the SAR and RGF. The specifications for the flight tests to gather airplane performance data are provided in Appendix A, including the formulas to be used to determine the SAR and RGF from data gathered during testing. The appendix also describes certification data that would be submitted to the FAA in the certification test report that is a part of fuel efficiency certification.

The FAA received comments on several sections of Appendix A to part 38. As a result of these comments, as well as consistency edits that result from the FAA's responses to these comments, the FAA has made changes to proposed paragraphs A38.1.2.3.1, A38.1.2.3.4, A38.2.1.1.3, A38.2.1.1.6,

A38.2.1.3.1, A38.2.1.3.2, A38.4.2.1.2, A38.4.2.1.3, A38.4.2.1.4.1, A38.4.2.1.4.2, A38.4.2.1.5.1, A38.4.2.1.5.2, A38.4.2.2, A38.4.2.2.1, A38.4.2.2.1.2, A38.4.2.2.1.4, A38.4.2.3.2.1, A38.4.2.3.2.2, A38.4.2.3.2.3, A38.5.2.2.1.1, A38.6, A38.6.1.2, A38.6.3.7, A38.6.3.9, and A38.6.4. In general, the comments pertained to clarifications on airplane weighing and mass requirements, fuel sampling requirements, fuel kinematic viscosity requirements, airplane trim requirements, the use of standard United States aerospace terminology, engine deterioration, corrections to reference specifications, the reporting of data, the fixing titles of reference citations, and some minor typographical errors.

Paragraph A38.2.1.3.1 identifies a reference specification for standard day atmosphere. As discussed in relation to § 38.7, the FAA has determined that this specification needs to be incorporated by reference and has indicated that in A38.2.1.3.1 as well as the other paragraphs that include this same reference specification (*i.e.*, paragraphs A38.5.2.2.1.9 and A38.5.2.2.1.10). Also, in paragraph A38.2.1.3.1, the FAA noticed that it inadvertently failed to include an "and" at the end of this paragraph, which is now included for consistency with the ICAO standard. The FAA corrected the section accordingly. In paragraphs 38.3.2, 38.3.3, and 38.3.4, this rule adopts changes from "cockpit" to "flight deck" to provide gender-neutral language without changing the meaning or intent. Other than these changes, the FAA adopts the Appendix as proposed.

2. Public Comments and FAA Response

The comments and responses below are categorized based on the relevant appendix section.

a. Appendix A to Part 38, A38.1 Introduction

Comment: For proposed paragraphs A38.1.2.3.1 and A38.1.2.3.4, Airbus noted potential errors including a missing "and" between listed requirements of a performance model, and incorrect numbering of appendix sections where A38.1.2.3.4 should have been A38.1.2.3.3.

Response: The FAA disagrees with the request to add an "and" at the end of A38.1.2.3.1. The FAA notes the proposal contained an "and" in the next to last item in the list and this is sufficient to make each of the items under A.38.1.2.3 a requirement. Thus, the FAA did not make this proposed change. However, with respect to the incorrect numbering in proposed

A38.1.2.3.4, the FAA agrees that this is a typographical error and has corrected it.

b. Appendix A to Part 38, A38.2 Reference Specifications for SAR Flight Tests

Comment: For paragraph A38.2.1.1.3, Boeing suggested using standard industry terminology of "unaccelerated" instead of "unaccelerating."

Response: The FAA agrees that "unaccelerated" is a more common aerospace industry terminology when describing steady-level flight, thus the FAA made the suggested changes. The FAA also made these same changes to paragraphs A38.4.2.2.1.2 and A38.5.2.2.1.

Comment: For paragraph A38.2.1.1.5, Gulfstream requested confirmation that, when it uses a performance model, all the provided information in the section will be embedded in the model and additional corrections will not be required in the model results.

Response: The FAA confirms that reference specifications are required for flight test data, which can be used to validate a performance model. Depending on how the performance model is built and on what data it is based, corrections may be necessary for SAR values calculated from the model.

c. Appendix A to Part 38, A38.4 Certification Test Specifications

Comment: For paragraph A38.4.2.1.2, Boeing requested to clarify the airplane weight and balance requirement by removing the words "prior to the test flight." Boeing indicated it may be possible that the weight before flight may not be the best engineering value; because test data may, after post-flight weighing, suggest a more optimal means for establishing accurate weight.

Response: The FAA agrees that this airplane weight requirement can be clarified, however disagrees with the proposed changes as they would cause a substantive difference (discussed in IV.F.) with the ICAO international standard that includes the words "prior to the test flight." The FAA has revised the text to align with the ICAO international standard by changing the requirement to read: "The test airplane must be weighed. Any change in mass after the weighing and prior to the test flight must be accounted for." During its review of this paragraph, the FAA recognized that the "and balance" text that was contained in the proposed A38.4.2.1.2 is not required given the various center of gravity requirements throughout Appendix A. After reviewing all center of gravity requirements in Appendix A, the FAA

made a clarifying change in A38.2.1.1.6 by changing “a” to “the” in the proposed text (*i.e.*, representative of a mid-CG point relevant to design cruise performance). The FAA’s clarifying change ensures there is no ambiguity as there is only one mid-CG point at each of the three reference airplane masses.

Comment: For paragraphs A38.4.2.1.3, A38.4.2.1.4.1, A38.4.2.1.5.1, and A38.4.2.1.5.2, Boeing suggested correcting these reference citations by: (1) removing the word “specification” when referring to the external American Society for Testing and Materials (ASTM) documents, and (2) correcting the titles of the documents as needed.

Response: The FAA agrees to these minor editorial changes and accepts them. The FAA also noticed, and corrected, that the word “titled” instead of “entitled” should have been used when quoting the titles of these documents.

Comment: For paragraph A38.4.2.1.4.2, Airbus suggested that it did not understand the text “and may not have variations” at the end of the fuel sample requirement, because fuel samples are analyzed for each test flight and a single lower heating value is determined.

Response: The FAA agrees with this reasoning and has revised the text to better align with the ICAO international standard regarding flexibility on variations and errors. The language now reads:

The fuel sample may be representative of the fuel used for each flight test and should not have errors or variations due to fuel being uplifted from multiple sources, fuel tank selection, or fuel layering in a tank.

Comment: For paragraph A38.4.2.1.5.2, Airbus requested an additional ASTM document be added for determining fuel kinematic viscosity.

Response: The FAA disagrees because it would result in a substantive difference (discussed in IV.F.) with the ICAO international standard. In addition, the FAA notes that the words “or as approved by the FAA” at the end of that paragraph allow applicants to seek approval of other methods for determining fuel kinematic viscosity, which is consistent with the ICAO standard.

Comment: An individual commented on paragraph A38.4.2.2 regarding the use of the term “configuration.” They indicated that this section relates to criteria, procedures, or requirements and that it does not relate to configurations, which is a term used for defining an airplane configuration such as a flap position, gear position, or some aspect of the type design.

Response: Upon review, the FAA acknowledges the word “configuration(s)” does not accurately reflect the requirement. The requirement relates more to procedures on how the pilot should fly the airplane during flight testing. As such, the FAA has replaced the word “configuration(s)” with the word “procedure(s)” in A38.4.2.2 and A38.4.2.2.1.

Comment: For paragraph A38.4.2.2.1.4, Boeing requested a change to the text “there are no changes in trim.” Boeing requested that the text be revised to allow some changes by stating that changes are to be avoided or minimized as practicable. Boeing explained that it may not be possible to eliminate all changes during flight because there may be unavoidable circumstances during flight; however, such changes may be accounted for through data analysis and interpretation.

Response: The FAA agrees that in-flight conditions may not make it possible to eliminate changes to some trim and engine settings, and that changes may be accounted for through post-flight data analysis. The FAA also notes that providing flexibility better aligns with the same recommendation in the ICAO international standard. Accordingly, the FAA revised the text to read as follows:

Changes in trim or engine power/thrust settings, engine stability and handling bleeds, or electrical and mechanical power extraction (including bleed flow) are avoided or minimized as practicable.

Comment: For paragraph A38.4.2.3.2, Airbus explained that the requirement regarding airplane mass determination should provide for alternative methods, specifically by changing the word “must” to “may.”

Response: The FAA agrees that this requirement should allow additional methods to determine the mass of the airplane because the ICAO Annex 16 Vol III also lists the two methods as recommended options for determining mass, not as required methods. Therefore, the FAA kept the word “must,” but added a third option to A38.4.2.3.2.3: other methods as approved by the FAA. This third option will allow alternative methods in addition to the two options listed.

d. Appendix A to Part 38, A38.5 Measurement of Specific Air Range

Comment: For paragraph A38.5.2.2.1.7, Airbus suggested the sentence starting with the text “(s)ince engine deterioration is rapid when . . .” may not be grammatically correct.

Response: The FAA notes that this is a partial sentence that is a lead-in to the two sub-paragraphs that follow it. In that context, the FAA does not see a need to make changes to this text.

Comment: For paragraph A38.5.2.2.1.7.2, Boeing suggested replacing the proposed text, “. . . and no correction is permitted” with, “. . . and a correction to the reference deterioration level may be approved by the FAA.” Boeing asserted that technology and processes have advanced to the point where it is reasonable to employ engine deterioration corrections in certain circumstances. Boeing noted that it has successfully employed deterioration corrections on occasion and believes that the FAA provide flexibility for deterioration corrections if the FAA approves of the correction.

Response: The FAA disagrees with providing the suggested flexibility for this requirement because this change would cause a substantive difference (discussed in IV.F.) with the ICAO international standard that precludes correction in these instances.

Comment: For paragraph A38.5.3, Gulfstream commented that it is unclear how an applicant will manage confidence intervals when a performance model is used.

Response: The AC38 provides guidance on determining and using confidence intervals.

e. Appendix A to Part 38, A38.6 Submission of Certification Data to the FAA

Comment: For paragraph A38.6, Airbus recommended edits to the proposed text to allow other analysis reports to convey the required information, not just the certification test report.

Report: The FAA agrees that there are various types of reports during certification that could contain the required information. The FAA made the change from “certification test report” to “certification reports.”

Comment: For paragraphs A38.6.1.2, A38.6.3.7, and A38.6.3.9, Airbus and Boeing noted typographical and reference errors, including a reference to § 38.23(a)(3) that does not exist in A38.6.1.2, a correction to a semicolon in A38.6.3.7, and incorrect references within A38.6.3.9.

Response: The FAA agrees and fixed the noted typographical and reference errors.

Comment: For paragraph A38.6.4, Airbus requested that the FAA remove the text “defined in § 38.13(b).” Airbus indicated that this language suggested that the test measurements are

systematically done at the reference masses of the standard but that this was not the case when a performance model was used.

Response: The FAA agrees that the reference to § 38.13(b) should be removed for the reasons Airbus stated and has removed the reference. In addition, the FAA's review resulted in the need to clarify this requirement in paragraph A38.6.4 by clearly stating that SAR values, corrections from measured data to reference specifications, and finally the SAR values calculated from corrected data must be provided for the test measurement points. As such, the requirement has been updated to the following language:

The measured SAR test data, all corrections of the measured data to the reference specifications, and the SAR values calculated from the corrected data must be provided.

S. Other Revisions to 14 CFR

The proposed rule set forth several amendments to part 21 to include compliance with part 38 as a requirement for type, supplemental type, or airworthiness certification using the applicability described in § 38.1. If adopted, the amendment proposed to part 21 would include adding references to part 38 in §§ 21.5, 21.17, 21.29, 21.31, 21.93, 21.101, 21.115, 21.183, and 21.187. The NPRM also proposed to adopt the move and redesignation of § 21.187(c) to § 21.187(a)(3). The proposal also included amendments to the operating regulations (§§ 121.141 and 125.75) for airplanes subject to part 38. The revisions were included to add the certification information for fuel efficiency to the airplane flight manuals.

1. Discussion of the Final Rule

With some changes, this rule adopts the proposed changes to part 21 and §§ 121.141 and 125.75.

In particular, in this final rule, the FAA also makes a change to § 21.93(d) by adding that a voluntary change that may increase the MTOM of that airplane is a "fuel efficiency change." The proposal only identified an increase in the FEM value as a "fuel efficiency change." This change was made to ensure consistency with the change criteria in § 38.19.

Further, as a result of comments, the FAA made changes to §§ 21.21, 21.93, and 121.141. These changes ensure that the fuel efficiency requirements are appropriately included in part 21 and corrected an inadvertent change in § 121.141. Other than these identified changes, the FAA adopts the amendments to part 21 and §§ 121.141 and 125.75 as proposed.

Finally, this rule adopts changes to § 21.187 to provide gender-neutral language (from "He" to "The applicant") without changing the meaning or intent of the rule.

The comments and responses are organized by the specific regulatory section.

2. Public Comments and FAA Response

a. Section 21.5: Airplane or Rotorcraft Flight Manual

Comment: One individual commenter recommended adding "Rotorcraft Flight Manual" to the change proposed in § 21.5(b)(3).

Response: The FAA does not concur with adding "Rotorcraft Flight Manual" to the changes in § 21.5(b)(3) to accommodate the addition of part 38 requirements as this rule only applies to fixed wing airplanes.

Comment: One commenter stated § 21.5 only pertains to airplanes and rotorcraft not type certificated with an Airplane or Rotorcraft Flight Manual and asked whether there were any such airplanes in existence that would be subject to part 38.

Response: Section 21.5 applies to all airplanes that do not have flight time prior to March 1, 1979. Airplanes produced or certified on or after that date are required to have an approved flight manual.

Comment: One individual proposed the airplane flight manual requirement should be placed in §§ 25.1581 and 23.2620. They stated that it was also unclear how the requirement in § 21.5 meshes with § 38.23. They thought the requirements of § 38.23 should either be placed in or reference the sections of parts 23 and 25 pertaining to Airplane Flight Manuals and airplane limitations.

Response: The FAA disagrees with the requested amendments to parts 23 and 25. Flight manual requirements are covered in the revised § 21.5. This final rule also amends the applicability requirements in other sections of part 21 such that § 21.5 applies to part 23 and 25 airplanes. Accordingly, the flight manuals for these airplanes must include the flight manual requirements of part 38.

b. Section 21.21: Issue of Type Certificate: Normal, Utility, Acrobatic, Commuter, and Transport Category Aircraft; Manned Free Balloons; Special Classes of Aircraft; Aircraft Engines; Propellers

Comment: Boeing recommended that the FAA revise § 21.21(b) and (b)(1) by adding "and fuel efficiency" to be consistent with proposed § 38.1(a)(1), (2) and (3) (for new-type airplanes

seeking original type certification). Boeing noted that adding "fuel venting and exhaust emissions" to § 21.21 would also be consistent with the FAA's revision of § 21.29.

Response: Section 21.21 identifies all the necessary requirements for receiving a type certificate. In order to fully effectuate part 38 into the type certification requirements, it is important to include this rule in paragraph (b) of this section. Further, the FAA agrees that consistency is necessary between §§ 21.21 and 21.29. Section 21.21 was revised to list fuel efficiency in addition to the other environmental requirements that an applicant must comply with in order to get a type certificate. The FAA has modified § 21.21 to include fuel efficiency.

The FAA inadvertently revised § 21.29 with a punctuation error in the proposed rule to state, "fuel venting and exhaust emissions, and fuel efficiency." The FAA has corrected this in the final rule to state "fuel venting, exhaust emission, and fuel efficiency" to be consistent with § 21.21.

c. Section 21.93: Classification of Changes in Type Design

Comments: Gulfstream requested clarity on the use of the word "voluntary" regarding type design changes in § 21.93(d). Gulfstream recollected that the ICAO language did not include the word "voluntary" and asked if it was the FAA's intent to protect applicants from having to reverify part 38 compliance after a mandated design change.

Response: The FAA's intent was to prevent applicants from having to reverify part 38 compliance after a mandated design change. The FAA uses the word "voluntary" to describe the action initiated by an applicant to obtain an approval. On the other hand, non-voluntary or mandated changes, typically required by an authority, are needed to maintain the airworthiness of in-service airplanes as soon as possible for safety concerns. The ICAO Standards and Recommended Practices do not have a similar exception for authority-mandated changes to an airplane. It is the responsibility of the authority adopting the Annexes to provide their own procedures for handling mandated changes required for continued operational safety.

Comments: Embraer noted that 14 CFR 21.93(d) defines the term 'fuel efficiency change' that is not used within 14 CFR part 38. This leaves the applicability definition of 14 CFR part 38 within § 38.19. On the other hand,

Embraer stated that ICAO/RBAC¹⁸ uses the definition of “derived version” to determine applicability. Although the definitions are similar, Embraer states this could generate interpretation problems when classifying a modification and, consequently, to define the involvement of the authorities.

Response: The FAA is not defining a new term “fuel efficiency change” as Embraer indicates. This language refers to changes in the certified “fuel efficiency metric value” as provided in part 38. The applicability of § 38.1 includes a direct reference to § 38.19 (see in § 38.1(b)) and, therefore, includes modifications as part of applicability considerations. Similarly, ICAO includes modifications via a definition of “derived versions” that is contained outside the applicability provisions.

d. Other Part 21 Sections

Comments: Boeing suggested adding additional text to §§ 21.101(a), 21.115(a)(3), 21.183(j), and 21.187(a)(4) that direct a reader to specific applicability sections of part 38. Boeing was concerned that, as drafted, these sections could mistakenly be read to mean that an obligation to demonstrate compliance with part 38 applies automatically upon any application for approval of a modification in type design for any airplane, including an in-service airplane, regardless of whether the requirements of §§ 38.1 and 38.19 are met.

Response: The FAA disagrees. Section 21.93(d) refers to part 38 for purposes of maintaining compliance with part 38. Part 38 is the appropriate regulatory location to determine which sections of part 38 apply in a particular circumstance.

Further, the FAA has revised the applicability requirements in part 38 to clarify its applicability to modifications in type design for any airplane, including an in-service airplane. See FAA’s responses to comments in section IV.D. For these reasons, the FAA is not adopting the suggested changes.

e. Section 121.141 (Airplane Flight Manual) and 125.75 (Airplane Flight Manual)

Comment: One individual commenter noted that changing the word “may” to “must” is a significant change in § 121.141(b), making it mandatory to revise the performance section of the Airplane Flight Manual when operators create their own manual. The commenter also noted that this change

was not consistent with the proposal to change § 125.75(b), which does not change a similar “must” in the existing text to “may.” The commenter also recommended that if FAA meant to change the language to “must” in § 121.141(b), the FAA should make a corresponding change in § 125.75(b) and explain the change in the preamble.

Response: The FAA concurs that the text added to § 121.141(b) should have said “may revise” not “must revise.” This was an inadvertent change from existing text. Accordingly, the final rule text is corrected to “may revise” and the FAA does not need to make the suggested change to § 125.75(b).

T. Costs

A number of individuals commented generally regarding their concerns about the monetary costs of the rule.

The FAA conducted an analysis of the costs and benefits of the proposed rule. As described in the preliminary regulatory impact analysis (RIA) that accompanied the proposal, in the absence of the FAA’s rule aircraft manufacturers would have to certify to the fuel efficiency standards through foreign authorities. As a result, the rule reduces the cost of this certification by enabling certification through the FAA. Therefore, the FAA does not expect this rule will impose an undue burden on industry, an increase in the cost of air travel, or other negative economic impacts commenters attribute to the rule. Regarding the need for government intervention, airplane fuel efficiency has increased as the standard is technology-following, but the rule prevents backsliding to less fuel-efficient airplanes. The FAA also noted that the rule may generate minimal benefits since the ICAO designed the standard in such a way that most airplanes would already meet the standard.

Boeing asserted that footnote 8 in the preliminary RIA contradicted the EPA’s unambiguous intent with respect to the inapplicability of its GHG standards to modifications of individual in-service airplanes. The footnote stated that owners or operators that modify an airplane that was not certificated to the proposed fuel efficiency standard may also need to comply with the rule when the modifications are made. The National Business Aviation Association (NBAA) also asserted that in the preliminary RIA, the FAA failed to analyze the financial impact this rule may have on the current fleet. Specifically, it stated that operators seeking to modify their airplanes through a Supplemental Type Certificate (STC) may have to complete additional modifications or data

analysis to meet the FEM, resulting in additional costs. The NBAA encouraged the FAA to consider this submission prior to applying this rule to modified airplanes.

The FAA asserts that there will be no economic impact on the current fleet stemming from this rule. The FAA agrees that owners or operators that modify an airplane that was not certificated to the fuel efficiency standards will not need to comply with the rule when those modifications are made. The rule does not apply to the in-service fleet that was not certified to the fuel efficiency standard, including any future modifications. As such, there will be no impact on the current fleet for operators seeking to modify their airplane through an STC. The FAA deleted the referenced footnote 8 in the final RIA.

V. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is \$177 million using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. The FAA has provided a detailed Regulatory Impact Analysis (RIA) in the docket for this rulemaking. This portion of the preamble summarizes the FAA’s analysis of the economic impacts of this rule.

In conducting these analyses, the FAA has determined that this rule: will result in benefits that justify costs; is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866, as amended by Executive Order 14094; will not have a significant

¹⁸ This is an acronym in Portuguese for Brazilian Regulations for Civil Aviation.

economic impact on a substantial number of small entities; will not create unnecessary obstacles to the foreign commerce of the United States; and will not impose an unfunded mandate on State, local, or Tribal governments, or on the private sector.

A. Summary of the Regulatory Impact Analysis

The FAA identified three United States manufacturers that would be affected by the rule. Manufacturers will incur certification costs even in the absence of the rule since they would pursue certification with foreign authorities. Certification tasks will vary greatly depending on the stage of the airplane development process (*e.g.*, new type certificate, supplemental type certificate, etc.). Additionally, the first fuel efficiency certification project undertaken by any one manufacturer may require more resources because of the new processes and the need for new data generation. The FAA used information provided by the affected airplane manufacturers to construct a timeline of when these costs would be incurred over a 10-year period, and the cost savings from domestic certification enabled by the rule.

Because the EPA standards apply to airplanes certificated in the United States even in the absence of the rule, there are no incremental benefits associated with the FAA's action; however, the rule will result in cost savings by enabling United States manufacturers to certify to the standards domestically. Annualized costs savings may be approximately \$0.4 million using discount rates of 3 percent and 7 percent (a present value over 10 years of \$3.5 million to \$2.9 million, using discount rates of 3 percent and 7 percent, respectively).

Please see the RIA available in the docket for more details.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) and the Small Business Jobs Act of 2010 (Pub. L. 111–240), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term “small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

As described in the RIA, the FAA identified three United States manufacturers that would be affected by the proposed rule. Based on the Small Business Administration (SBA) size standard for aircraft manufacturing (Table 1), all three manufacturers are large businesses. If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b) and based on the foregoing, the head of FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

TABLE 1—SMALL BUSINESS SIZE STANDARDS: AIR TRANSPORTATION

NAICS code	Description	Size standard
336411	Aircraft manufacturing.	1,500 employees.

Source: SBA (2022).¹⁹
NAICS = North American Industrial Classification System.

C. International Trade Impact Assessment

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 standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for United States standards.

The FAA has assessed the potential effects of this rule and finds that it does not create an unnecessary obstacle to foreign commerce. The United States has adopted the same airplane emission standards as ICAO and many of its member States. This rule is the next step in insuring compliance with the internationally recognized standard.

¹⁹ Small Business Administration (SBA). 2022. Table of Size Standards. Effective July 14, 2022. www.sba.gov/document/support-table-size-standards.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA determined that this final rule will not result in the expenditure of \$177 million or more by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

This rule does not contain such a mandate; therefore, the requirements of title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

This action contains the following new information collection requirement. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted these information collection amendments to OMB for its review. The OMB control number for this action is 2120–0815.

Summary

The regulations, adding a new part 38 to 14 CFR that requires certification for fuel efficiency, includes a collection of data from certification applicants. Certain data collected by the respondent during its certification flight tests are to be included in a certification test report that is submitted to the FAA. Those data are described in Appendix A to part 38. The information in the test report is used by the agency to determine whether the subject airplane complies with the fuel efficiency requirements promulgated by the EPA and the FAA. Without such information, the FAA would not have the complete record of an airplane's fuel efficiency performance and would be unable to issue a type or airworthiness certificate.

Use

Respondent's data will be used to determine compliance with the fuel efficiency standards established by the

EPA under the requirements of the Clean Air Act. The FAA is required by the Clean Air Act to implement those standards, which is done at the time of airplane certification.

Respondent's test data will not be maintained by the FAA following a certification determination. The certification test report is not available to the public. The regulation also requires that certain values be listed in the flight manual of the airplane, which is given to the purchaser of an airplane.

Respondents (including number of): The FAA anticipates three respondents to the collection of information.

Frequency: The FAA anticipates that respondents will provide responses annually (averaged).

Annual Burden Estimate: Table 1 provides the FAA's estimates of annual reporting (submission of certification data) and recordkeeping (manual information) burden.

TABLE 1—SUMMARY OF ANNUAL BURDEN

Category	Reporting	Recordkeeping
# of respondents	3	3
# of responses per respondent	2	2
Time per response (hours)	2	8
Total # of responses	6	6
Total burden (hours)	12	48

F. International Compatibility

In keeping with United States' obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no substantive differences with these regulations.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act (NEPA) in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the

categorical exclusion identified in paragraph 5–6.6f for regulations and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order (E.O.) 13132, Federalism. The FAA has determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, will not have federalism implications.

B. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments,²⁰ and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,²¹ the FAA ensures that Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes; or to affect uniquely or significantly their respective Tribes. At this point, the FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this final rule.

C. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The FAA has determined that it is not a “significant energy action” under the executive order and not likely to have a significant adverse effect on the supply, distribution, or use of energy.

²⁰ 65 FR 67249 (Nov. 6, 2000).

²¹ FAA Order No. 1210.20 (Jan. 28, 2004), available at www.faa.gov/documentLibrary/media/1210.pdf.

D. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policy and agency responsibilities of Executive Order 13609. The FAA has determined that this action will eliminate differences between United States aviation standards and those of other civil aviation authorities by adopting the airplane certification regulations needed to comply with the standards adopted by ICAO and the EPA.

VII. Additional Information

A. Electronic Access and Filing

A copy of the NPRM, all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the docket number listed above. A copy of this final rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at www.federalregister.gov and the Government Publishing Office's website at www.govinfo.gov. A copy may also be found at the FAA's Regulations and Policies website at www.faa.gov/regulations_policies.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this final rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT**

heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects

14 CFR Part 21

Aircraft, Aviation safety, Exports, Imports, Reporting and recordkeeping requirements.

14 CFR Part 38

Air Pollution Control, Aircraft, Incorporation by reference.

14 CFR Part 121

Air carriers, Aircraft, Airmen, Alcohol abuse, Aviation safety, Charter flights, Drug abuse, Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 125

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 21—CERTIFICATION PROCEDURES FOR PRODUCTS AND ARTICLES

■ 1. The authority citation for part 21 continues to read as follows:

Authority: 42 U.S.C. 7572; 49 U.S.C. 106(f), 106(g), 40105, 40113, 44701–44702, 44704, 44707, 44709, 44711, 44713, 44715, 45303.

■ 2. Amend § 21.5 by adding paragraph (b)(3) to read as follows:

§ 21.5 Airplane or Rotorcraft Flight Manual.

* * * * *

(b) * * *

(3) Documentation of compliance with part 38 of this chapter, in an FAA-approved section of any approved airplane flight manual. Such material must include the fuel efficiency metric value as calculated under § 38.11 of this chapter, and the specific paragraph of § 38.17 of this chapter with which compliance has been shown for that airplane.

■ 3. Amend § 21.17 by revising paragraph (a) introductory text to read as follows:

§ 21.17 Designation of applicable regulations.

(a) Except as provided in §§ 25.2, 27.2, and 29.2 of this subchapter, and in

parts 26, 34, 36, and 38 of this subchapter, an applicant for a type certificate must show that the aircraft, aircraft engine, or propeller concerned meets—

* * * * *

■ 4. Amend § 21.21 by revising paragraphs (b) introductory text and (b)(1) to read as follows:

§ 21.21 Issue of type certificate: normal, utility, acrobatic, commuter, and transport category aircraft; manned free balloons; special classes of aircraft; aircraft engines; propellers.

* * * * *

(b) The applicant submits the type design, test reports, and computations necessary to show that the product to be certificated meets the applicable airworthiness, aircraft noise, fuel venting, exhaust emission, and fuel efficiency requirements of this subchapter and any special conditions prescribed by the FAA, and the FAA finds—

(1) Upon examination of the type design, and after completing all tests and inspections, that the type design and the product meet the applicable noise, fuel venting, emissions, and fuel efficiency requirements of this subchapter, and further finds that they meet the applicable airworthiness requirements of this subchapter or that any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and

* * * * *

■ 5. Amend § 21.29 by revising paragraphs (a)(1)(i) and (b) to read as follows:

§ 21.29 Issue of type certificate: import products.

(a) * * *

(1) * * *

(i) The applicable aircraft noise, fuel venting, exhaust emissions, and fuel efficiency requirements of this subchapter as designated in § 21.17, or the applicable aircraft noise, fuel venting, exhaust emissions, and fuel efficiency requirements of the State of Design, and any other requirements the FAA may prescribe to provide noise, fuel venting, exhaust emission, and fuel efficiency levels no greater than those provided by the applicable aircraft noise, fuel venting, exhaust emissions, and fuel efficiency requirements of this subchapter as designated in § 21.17; and

* * * * *

(b) A product type certificated under this section is determined to be compliant with the fuel venting and exhaust emission standards of part 34 of this subchapter, the noise standards of

part 36 of this subchapter, and the fuel efficiency requirements of part 38 of this subchapter. Compliance with parts 34, 36, and 38 of this subchapter is certified under paragraph (a)(1)(i) of this section, and the applicable airworthiness standards of this subchapter, or an equivalent level of safety, with which compliance is certified under paragraph (a)(1)(ii) of this section.

■ 6. Amend § 21.31 by revising paragraph (e) to read as follows:

§ 21.31 Type design.

* * * * *

(e) Any other data necessary to allow, by comparison, the determination of the airworthiness, noise characteristics, fuel efficiency, fuel venting, and exhaust emissions (where applicable) of later products of the same type.

■ 7. Amend § 21.93 by adding paragraph (d) to read as follows:

§ 21.93 Classification of changes in type design.

* * * * *

(d) For the purpose of maintaining compliance with part 38 of this chapter, any voluntary change in the type design of an airplane that may increase the fuel efficiency metric value or the MTOM of that airplane is a “fuel efficiency change”, in addition to being a minor or major change as classified in paragraph (a) of this section.

■ 8. Amend § 21.101 by revising paragraph (a) to read as follows:

§ 21.101 Designation of applicable regulations.

(a) An applicant for a change to a type certificate must show that the change and areas affected by the change comply with the airworthiness requirements applicable to the category of the product in effect on the date of the application for the change and with parts 34, 36, and 38 of this chapter. Exceptions are detailed in paragraphs (b) and (c) of this section.

* * * * *

■ 9. Amend § 21.115 by revising paragraph (a) to read as follows:

§ 21.115 Applicable requirements.

(a) Each applicant for a supplemental type certificate must show that the altered product meets applicable requirements specified in § 21.101 and—

(1) In the case of an acoustical change described in § 21.93(b), show compliance with the applicable noise requirements of part 36 of this chapter;

(2) In the case of an emissions change described in § 21.93(c), show compliance with the applicable fuel venting and exhaust emissions

requirements of part 34 of this chapter; and

(3) In the case of a fuel efficiency change described in § 21.93(d), show compliance with the applicable fuel efficiency requirements of part 38 of this chapter.

* * * * *

■ 10. Amend § 21.183 by adding reserved paragraph (i) and adding paragraph (j) to read as follows:

§ 21.183 Issue of standard airworthiness certificates for normal, utility, acrobatic, commuter, and transport category aircraft; manned free balloons; and special classes of aircraft.

* * * * *

(i) [Reserved]

(j) *Fuel efficiency requirements.* No original standard airworthiness certificate may be issued under this section unless the applicant has demonstrated that the type design complies with the applicable fuel efficiency requirements of part 38 of this chapter.

■ 11. Amend § 21.187 by revising paragraph (a) to read as follows:

§ 21.187 Issue of multiple airworthiness certification.

(a) An applicant for an airworthiness certificate in the restricted category, and in one or more other categories except primary category, is entitled to the certificate, if—

(1) The applicant shows compliance with the requirements for each category, when the aircraft is in the configuration for that category;

(2) The applicant shows that the aircraft can be converted from one category to another by removing or adding equipment by simple mechanical means;

(3) The aircraft complies with the applicable requirements of part 34 of this subchapter; and

(4) The airplane complies with the applicable requirements of part 38 of this subchapter.

* * * * *

■ 12. Add part 38 to read as follows:

PART 38—AIRPLANE FUEL EFFICIENCY CERTIFICATION

Subpart A—General

Sec.

38.1 Applicability.

38.3 Definitions.

38.4 Compatibility with airworthiness requirements.

38.5 Exemptions.

38.7 Incorporation by reference.

38.9 Relationship to other regulations.

Subpart B—Determining Fuel Efficiency for Subsonic Airplanes

38.11 Fuel efficiency metric.

38.13 Specific air range.

38.15 Reference geometric factor.

38.17 Fuel efficiency limits.

38.19 Change criteria.

38.21 Approval before compliance testing.

38.23 Manual information and limitations.

Appendix A to Part 38—Determination of Airplane Fuel Efficiency Metric Value

Authority: 42 U.S.C. 4321 *et seq.*, 7572; 49 U.S.C. 106(g), 40113, 44701–44702, 44704; 49 CFR 1.83(c)

Subpart A—General

§ 38.1 Applicability.

(a) Except as provided in paragraph (c) of this section, an airplane that is subject to the requirements of 40 CFR part 1030 may not exceed the fuel efficiency limits of this part when original type certification under this title is sought. This part applies to the following airplanes:

(1) A subsonic jet airplane that has—

(i) Either—

(A) A type-certificated maximum passenger seating capacity of 20 seats or more;

(B) A maximum takeoff mass (MTOM) greater than 5,700 kg; and

(C) An application for original type certification that is submitted on or after January 11, 2021;

(ii) Or—

(A) A type-certificated maximum passenger seating capacity of 19 seats or fewer;

(B) A MTOM greater than 60,000 kg; and

(C) An application for original type certification that is submitted on or after January 11, 2021.

(2) A subsonic jet airplane that has—

(i) A type-certificated maximum passenger seating capacity of 19 seats or fewer;

(ii) A MTOM greater than 5,700 kg, but not greater than 60,000 kg; and

(iii) An application for original type certification that is submitted on or after January 1, 2023.

(3) A propeller-driven airplane that has—

(i) A MTOM greater than 8,618 kg; and

(ii) An application for original type certification that is submitted on or after January 11, 2021.

(4) A subsonic jet airplane—

(i) That is a modified version of an airplane whose type design was not certificated under this part;

(ii) That has a MTOM greater than 5,700 kg;

(iii) For which an application by the type certificate holder for a type design change is submitted on or after January 1, 2023; and

(iv) For which the first certificate of airworthiness is issued with the modified type design.

(5) A propeller-driven airplane—

(i) That is a modified version of an airplane whose type design was not certificated under this part;

(ii) That has a MTOM greater than 8,618 kg;

(iii) For which an application by the type certificate holder for a type design change is submitted on or after January 1, 2023; and

(iv) For which the first certificate of airworthiness is issued with the modified type design.

(6) A subsonic jet airplane that has—

(i) A MTOM greater than 5,700 kg; and

(ii) Its first certificate of airworthiness issued on or after January 1, 2028.

(7) A propeller-driven airplane that has—

(i) A MTOM greater than 8,618 kg; and

(ii) Its first certificate of airworthiness issued on or after January 1, 2028.

(b) The requirements of this part apply to an airplane for which an application for a change in type design is submitted that includes a modification that meets the change criteria of § 38.19. A modified airplane may not exceed the applicable fuel efficiency limit of this part when certification under this chapter is sought. A modified airplane is subject to the same fuel efficiency limit of § 38.17 as the airplane was certificated to prior to modification.

(c) The requirements of this part do not apply to:

(1) Subsonic jet airplanes having a MTOM at or below 5,700 kg.

(2) Propeller-driven airplanes having a MTOM at or below 8,618 kg.

(3) Amphibious airplanes.

(4) Airplanes initially designed, or modified and used, for specialized operations. These airplane designs may include characteristics or configurations necessary to conduct specialized operations that the FAA and the United States Environmental Protection Agency (EPA) have determined may cause a significant increase in the fuel efficiency metric value.

(5) Airplanes designed with a reference geometric factor of zero.

(6) Airplanes designed for, or modified and used for, firefighting.

(7) Airplanes powered by reciprocating engines.

§ 38.3 Definitions.

For the purpose of showing compliance with this part, the following terms have the specified meanings:

Amphibious airplane means an airplane that is capable of takeoff and

landing on both land and water. Such an airplane uses its hull or floats attached to the landing gear for takeoff and landing on water, and either extendable or fixed landing gear for takeoff and landing on land.

ICAO Annex 16, Volume III means Volume III of Annex 16 to the Convention on International Civil Aviation.

Maximum takeoff mass (MTOM) is the maximum certified takeoff mass, expressed in kilograms, for an airplane type design.

Performance model is an analytical tool (or a method) validated using corrected flight test data that can be used to determine the specific air range values for calculating the fuel efficiency metric value.

Reference geometric factor (RGF) is a non-dimensional number derived from a two-dimensional projection of the fuselage.

Specific air range (SAR) is the distance an airplane travels per unit of fuel consumed. Specific air range is expressed in kilometers per kilogram of fuel.

Subsonic means an airplane that has not been certificated under this title to exceed Mach 1 in normal operation.

Type certificated maximum passenger seating capacity means the maximum number of passenger seats that may be installed on an airplane as listed on its type certificate data sheet, regardless of the actual number of seats installed on an individual airplane.

§ 38.4 Compatibility with airworthiness requirements.

Unless otherwise approved by the FAA, an airplane used to demonstrate compliance with this part must meet all

of the airworthiness requirements of this chapter required to establish the type certification basis of the airplane, for any condition under which compliance with this part is being demonstrated. Any procedure used to demonstrate compliance, and any flight crew information developed for demonstrating compliance with this part, must be consistent with the airworthiness requirements of this chapter that constitute the type certification basis of the airplane.

§ 38.5 Exemptions.

A petition for exemption from any requirement of this part must be submitted to the Administrator in accordance with and meet the requirements of part 11 of this chapter. The FAA will consult with the EPA on each exemption petition before taking action.

§ 38.7 Incorporation by reference.

The ICAO Doc 7488/3, *Manual of the ICAO Standard Atmosphere (extended to 80 kilometres (262 500 feet))* (1993), referenced in sections A38.2.1.3.1, A38.5.2.2.1.9, and A38.5.2.2.1.10 of appendix A to this part, is incorporated by reference into this part 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 the FAA and at the National Archives and Records Administration (NARA). Contact FAA at: Office of Rulemaking (ARM-1), 800 Independence Avenue SW, Washington, DC 20590 (telephone 202-267-9677). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email

fr.inspection@nara.gov. The ICAO Doc 7488/3 is available for purchase from the ICAO Store at 999 Robert-Bourassa Boulevard Montréal (Quebec) Canada H3C 5H7, (<https://store.icao.int/>).

§ 38.9 Relationship to other regulations.

In accordance with certain provisions of the Clean Air Act Amendments of 1970 (CAA) (42 U.S.C. 7571 *et seq.*), the United States Environmental Protection Agency (EPA) is authorized to set standards for aircraft engine emissions in the United States, while the FAA is authorized to ensure compliance with those standards under a delegation from the Secretary of Transportation (49 CFR 1.83). The fuel efficiency limits in § 38.17 are intended to be the same as that promulgated by the EPA in 40 CFR part 1030. Accordingly, if the EPA changes any regulation in 40 CFR part 1030 that corresponds with a regulation in this part, a certification applicant may request a waiver of those provisions as they appear in this part in order to comply with part 1030. In addition, unless otherwise specified in this part, all terminology and abbreviations in this part that are defined in 40 CFR part 1030 have the meaning specified in part 1030.

Subpart B—Determining Fuel Efficiency for Subsonic Airplanes

§ 38.11 Fuel efficiency metric.

For each airplane subject to this part, or to determine whether a modification makes an airplane subject to this part under the change criteria of § 38.19, a fuel efficiency metric value must be calculated, using the following equation, rounded to three decimal places:

$$\text{Fuel Efficiency metric value} = \frac{\left(\frac{1}{\text{SAR}}\right)_{\text{avg}}}{\text{RGF}^{0.24}}$$

Where:

The SAR is determined in accordance with § 38.13, and the RGF is determined in accordance with § 38.15. The fuel efficiency metric value is expressed in units of kilograms of fuel consumed per kilometer.

§ 38.13 Specific air range.

(a) For each airplane subject to this part, the SAR of an airplane must be determined by either:

- (1) Direct flight test measurements; or
- (2) Using a performance model that is:
 - (i) Validated by actual SAR flight test data; and

(ii) Approved by the FAA before any SAR calculations are submitted.

(b) For the airplane model, establish a 1/SAR value at each of the following reference airplane masses:

- (1) High gross mass: 92 percent MTOM.
- (2) Low gross mass: $(0.45 * \text{MTOM}) + (0.63 * (\text{MTOM}^{0.924}))$.
- (3) Mid gross mass: simple arithmetic average of high gross mass and low gross mass.

(c) To obtain $(1/\text{SAR})_{\text{avg}}$ as required to determine the fuel efficiency metric value described in § 38.11, calculate the average of the three 1/SAR values

described in paragraph (b) of this section. Do not include auxiliary power units in any 1/SAR calculation.

(d) All determinations made under this section must be made in accordance with the procedures applicable to SAR as described in appendix A to this part.

§ 38.15 Reference geometric factor.

For each airplane subject to this part, determine the airplane's non-dimensional RGF for the fuselage size of each airplane model, calculated as follows:

- (a) For an airplane with a single deck, determine the area of a surface

(expressed in m^2) bounded by the maximum width of the fuselage outer mold line projected to a flat plane parallel with the main deck floor and the forward and aft pressure bulkheads except for the crew flight deck zone.

(b) For an airplane with more than one deck, determine the sum of the areas (expressed in m^2) as follows:

(1) The maximum width of the fuselage outer mold line, projected to a flat plane parallel with the main deck floor by the forward and aft pressure

bulkheads except for any crew flight deck zone.

(2) The maximum width of the fuselage outer mold line at or above each other deck floor, projected to a flat plane parallel with the additional deck floor by the forward and aft pressure bulkheads except for any crew flight deck zone.

(c) Determine the non-dimensional RGF by dividing the area defined in paragraph (a) or (b) of this section by $1 m^2$.

(d) All measurements and calculations used to determine the RGF

of an airplane must be made in accordance with the procedures for determining RGF in section A38.3 of appendix A to this part.

§ 38.17 Fuel efficiency limits.

(a) The fuel efficiency limits in this section are expressed as maximum permitted fuel efficiency metric values, as calculated under § 38.11.

(b) The fuel efficiency metric value of an airplane subject to this part may not exceed the following, rounded to three decimal places:

For airplanes described in...	With a MTOM...	The maximum permitted fuel efficiency metric value is...
(1) Section 38.1(a)(1) and (2)	$5,700 < \text{MTOM} \leq 60,000 \text{ kg}$	$10^{(-2.73780 + (0.681310 * \log_{10}(\text{MTOM})) + (-0.0277861 * (\log_{10}(\text{MTOM}))^2))}$
(2) Section 38.1(a)(3)	$8,618 < \text{MTOM} \leq 60,000 \text{ kg}$	$10^{(-2.73780 + (0.681310 * \log_{10}(\text{MTOM})) + (-0.0277861 * (\log_{10}(\text{MTOM}))^2))}$
(3) Section 38.1(a)(1) and (3)	$60,000 < \text{MTOM} \leq 70,395 \text{ kg}$	0.764
(4) Section 38.1(a)(1) and (3)	$\text{MTOM} > 70,395 \text{ kg}$	$10^{(-1.412742 + (-0.020517 * \log_{10}(\text{MTOM})) + (0.0593831 * (\log_{10}(\text{MTOM}))^2))}$
(5) Section 38.1(a)(4) and (6)	$5,700 < \text{MTOM} \leq 60,000 \text{ kg}$	$10^{(-2.57535 + (0.609766 * \log_{10}(\text{MTOM})) + (-0.0191302 * (\log_{10}(\text{MTOM}))^2))}$
(6) Section 38.1(a)(5) and (7)	$8,618 < \text{MTOM} \leq 60,000 \text{ kg}$	$10^{(-2.57535 + (0.609766 * \log_{10}(\text{MTOM})) + (-0.0191302 * (\log_{10}(\text{MTOM}))^2))}$
(7) Section 38.1(a)(4) through (7)	$60,000 < \text{MTOM} \leq 70,107 \text{ kg}$	0.797
(8) Section 38.1(a)(4) through (7)	$\text{MTOM} > 70,107 \text{ kg}$	$10^{(-1.39353 + (-0.020517 * \log_{10}(\text{MTOM})) + (0.0593831 * (\log_{10}(\text{MTOM}))^2))}$

§ 38.19 Change criteria.

(a) For an airplane that has been shown to comply with § 38.17, any subsequent version of that airplane must demonstrate compliance with § 38.17 if the subsequent version incorporates a modification that either increases:

(1) The maximum takeoff mass; or
(2) The fuel efficiency metric value by a percentage that is more than the following calculated thresholds.

(i) For airplanes with a MTOM greater than or equal to 5,700 kg, the threshold decreases linearly from 1.35 percent for an airplane with a MTOM of 5,700 kg to 0.75 percent for an airplane with a MTOM of 60,000 kg.

(ii) For airplanes with a MTOM greater than or equal to 60,000 kg, the threshold decreases linearly from 0.75 percent for an airplane with a MTOM of 60,000 kg to 0.70 percent for airplanes with a MTOM of 600,000 kg.

(iii) For airplanes with a MTOM greater than or equal to 600,000 kg, the threshold is 0.70 percent.

(b) For an airplane that has been shown to comply with § 38.17, and for any subsequent version of that airplane that incorporates modifications that do not increase the MTOM or the fuel efficiency metric value in excess of the levels shown in paragraph (a) of this section, the fuel efficiency metric value of the modified airplane may be reported to be the same as the value prior to modification.

(c) For an airplane that meets the criteria of § 38.1(a)(4) or (5), on or after January 1, 2023, and before January 1, 2028, the airplane must demonstrate compliance with § 38.17 if it incorporates any modification that increases the fuel efficiency metric value of the airplane prior to modification by more than 1.5 percent.

§ 38.21 Approval before compliance testing.

All procedures, weights, configurations, and other information or data that are used to establish a fuel efficiency level required by this part or in any appendix to this part (including any equivalent procedures) must be approved by the FAA prior to use in certification tests intended to demonstrate compliance with this part.

§ 38.23 Manual information and limitations.

(a) *Information in manuals.* The following information must be included in any FAA-approved section of a FAA-approved Airplane Flight Manual or combination of approved manual material:

(1) Fuel efficiency level established as required by this part; and

(2) Maximum takeoff mass at which fuel efficiency level was established.

(b) *Limitation.* If the fuel efficiency of an airplane is established at a weight (mass) that is less than the maximum certificated takeoff weight (mass) used to establish the airworthiness of the airplane under this chapter, the lower weight (mass) becomes an operating limitation of the airplane and that limitation must be included in the limitations section of any FAA-approved manual.

Appendix A to Part 38—Determination of Airplane Fuel Efficiency Metric Value**A38.1 Introduction****A38.2 Reference specifications for SAR flight tests****A38.3 Determination of reference geometric factor (RGF)****A38.4 Certification test specifications****A38.5 Measurement of specific air range****A38.6 Submission of certification data to the FAA****A38.1 Introduction**

A38.1.1 This appendix describes the processes and procedures for determining the fuel efficiency metric value for an airplane subject to this part.

A38.1.2 Methods for Determining Specific Air Range (SAR)

A38.1.2.1 SAR may be determined by either—

A38.1.2.1.1 Direct flight test measurement at the SAR test points, including any corrections of test data to reference specifications; or

A38.1.2.1.2 Use of a performance model.

A38.1.2.2 For any determination made under section A38.1.2.1.1 of this appendix, the SAR flight test data must have been acquired in accordance with the procedures defined in this appendix and approved by the FAA.

A38.1.2.3 For any determination made under section A38.1.2.1.2 of this appendix, the performance model must:

A38.1.2.3.1 Be verified that the model produces the values that are the same as FAA-approved SAR flight test data;

A38.1.2.3.2 Include a detailed description of any test and analysis method and any algorithm used so as to allow evaluation by the FAA; and

A38.1.2.3.3 Be approved by the FAA before use.

A38.2 Reference Specifications for SAR Flight Tests

A38.2.1 The following reference specifications must be established when determining SAR values for an airplane. No reference specification may exceed any airworthiness limit approved for the airplane under this chapter. See section A38.5 of this appendix for further information.

A38.2.1.1 Reference specifications at the airplane level:

A38.2.1.1.1 Airplane at the reference masses listed in § 38.13(b);

A38.2.1.1.2 A combination of altitude and airspeed selected by the applicant;

A38.2.1.1.3 Airplane in steady, unaccelerated, straight and level flight;

A38.2.1.1.4 Airplane in longitudinal and lateral trim;

A38.2.1.1.5 Airplane gravitational acceleration when travelling in the direction of true North in still air at the reference altitude and a geodetic latitude of 45.5 degrees, based on g_0 is 9.80665 m/s², which is the standard acceleration due to gravity at sea level and a geodetic latitude of 45.5 degrees;

A38.2.1.1.6 A reference airplane center of gravity (CG) position selected by the applicant to be representative of the mid-CG point relevant to design cruise performance at each of the three reference airplane masses; and

A38.2.1.1.7 A wing structural loading condition defined by the applicant that is representative of operations conducted in accordance with the airplane's maximum payload capability.

A38.2.1.2 Reference specifications at the engine level:

A38.2.1.2.1 Electrical and mechanical power extraction and bleed flow relevant to design cruise performance, as selected by the applicant;

Note 1 to A38.2.1.2.1—Power extraction and bleed flow attributable to the use of optional equipment such as passenger entertainment systems need not be included.

A38.2.1.2.2 Engine stability bleeds operating according to the manufacturer's normal schedule for the engine; and

A38.2.1.2.3 Engines with at least 15 cycles or 50 engine flight hours.

A38.2.1.3 Other reference specifications:

A38.2.1.3.1 ICAO standard day atmosphere (Doc 7488/3, 3rd edition 1993, titled "Manual of the ICAO Standard Atmosphere (extended to 80 kilometres (262 500 feet))") (incorporated by reference, see § 38.7); and

A38.2.1.3.2 Fuel lower heating value equal to 43.217 MJ/kg (18, – 580 BTU/lb).

A38.2.2 If any test conditions are not the same as the reference specifications of this appendix, the test conditions must be corrected to the reference specifications as described in section A38.5 of this appendix.

A38.3 Determination of Reference Geometric Factor (RGF)

A38.3.1 This section provides additional information for determining the RGF, as required by § 38.15.

A38.3.2 The area that defines RGF includes all pressurized space on a single or multiple decks including aisles, assist spaces, passageways, stairwells and areas that can accommodate cargo or auxiliary fuel containers. It does not include permanent integrated fuel tanks within the cabin, or any unpressurized fairings, crew rest or work areas, or cargo areas that are not on the main or upper deck (e.g., 'loft' or under floor areas). RGF does not include the flight deck crew zone.

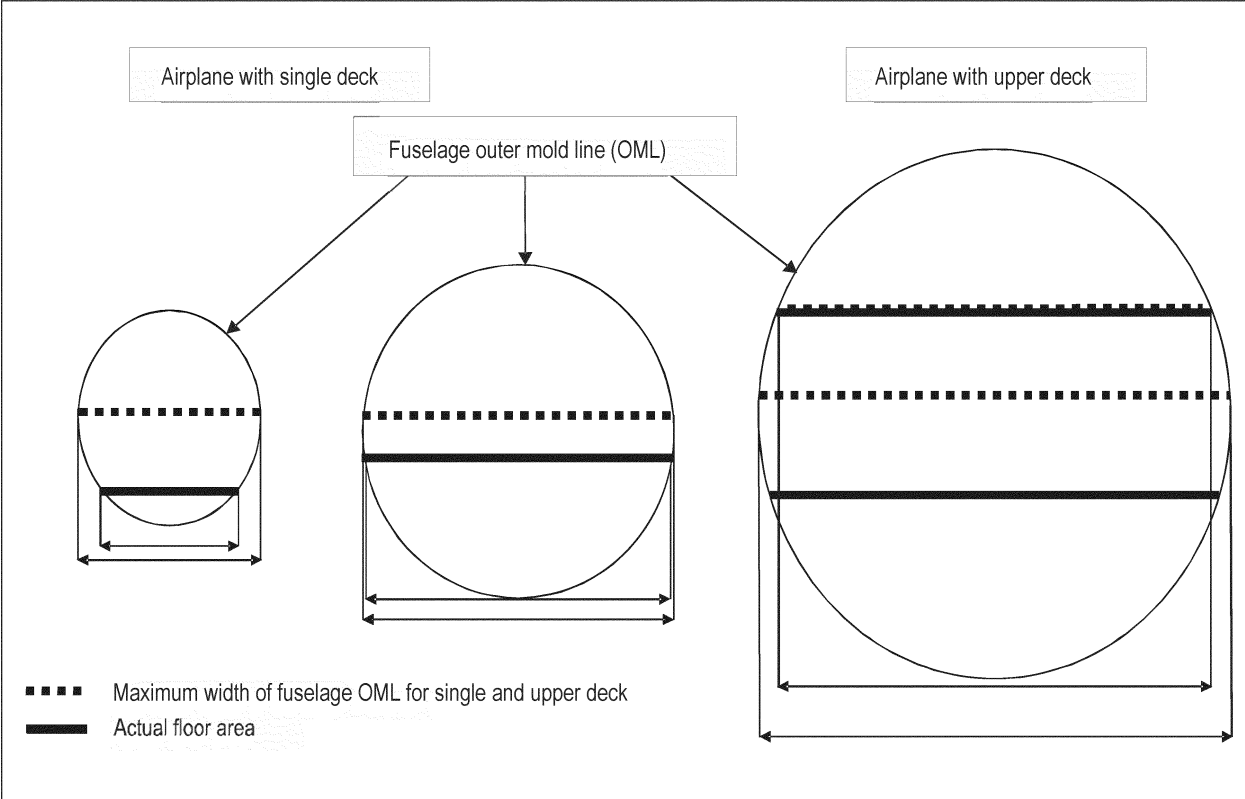
A38.3.3 The aft boundary to be used for calculating RGF is the aft pressure bulkhead. The forward boundary is the forward pressure bulkhead, not including the flight deck crew zone.

A38.3.4 Areas that are accessible to both crew and passengers are not considered part of the flight deck crew zone. For an airplane that has a flight deck door, the aft boundary of the flight deck crew zone is the plane of the flight deck door. For an airplane that has

no flight deck door or has optional interior configurations that include different locations of the flight deck door, the aft boundary is determined by the configuration that provides the smallest available flight deck crew zone. For airplanes certificated for

single-pilot operation, the flight deck crew zone is measured as half the width of the flight deck.
A38.3.5 Figures A38–1 and A38–2 of this appendix provide a notional view of the RGF boundary conditions.

Figure A38-1 to Appendix A to Part 38—Cross-sectional view



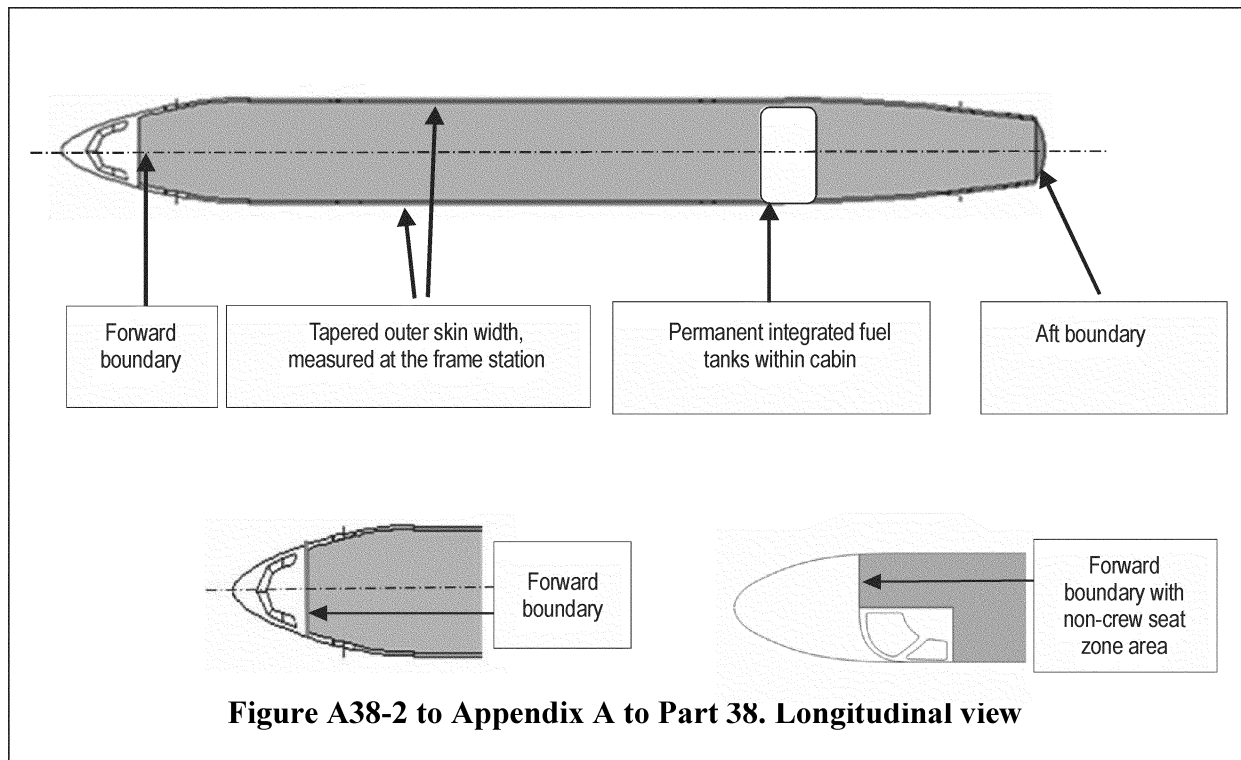


Figure A38-2 to Appendix A to Part 38. Longitudinal view

A38.4 Certification Test Specifications

A38.4.1 Certification Test Specifications. This section prescribes the specifications under which an applicant must conduct SAR certification tests.

A38.4.2 Flight Test Procedures

A38.4.2.1 Before a Test Flight. The test flight procedures must include the following elements and must be approved by the FAA before any test flight is conducted:

A38.4.2.1.1 Airplane conformity. The test airplane must conform to the critical configuration of the type design for which certification is sought.

A38.4.2.1.2 Airplane weight. The test airplane must be weighed. Any change in mass after the weighing and prior to the test flight must be accounted for.

A38.4.2.1.3 Fuel. The fuel used for each flight test must meet the specification defined in either ASTM D1655–15 (titled “Standard Specification for Aviation Turbine Fuels”), UK MoD Defense Standard 91–91, Issue 7, Amendment 3 (titled “Turbine Fuel, Kerosene Type, Jet A–1, NATO Code F–35; Join Services Designation; AVTUR”), or as approved by FAA.

A38.4.2.1.4 Fuel lower heating value. The lower heating value of the fuel used on a test flight must be determined from a sample of fuel used for the test flight. The lower heating value of the fuel sample must be used to correct measured data to reference

specifications. The determination of lower heating value and the correction to reference specifications are subject to approval by the FAA.

A38.4.2.1.4.1 The fuel lower heating value may be determined in accordance with ASTM D4809–13 “Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter (Precision Method)”, or as approved by the FAA.

A38.4.2.1.4.2 The fuel sample may be representative of the fuel used for each flight test and should not have errors or variations due to fuel being uplifted from multiple sources, fuel tank selection, or fuel layering in a tank.

A38.4.2.1.5 Fuel specific gravity and viscosity. When volumetric fuel flow meters are used, the specific gravity and viscosity of the fuel used on a test flight must be determined from a sample of fuel used for the test flight.

A38.4.2.1.5.1 The fuel specific gravity may be determined in accordance with ASTM D4052–11 “Standard Test Method for Density, Relative Density, and API Gravity of Liquids”, or as approved by FAA.

A38.4.2.1.5.2 The fuel kinematic viscosity may be determined in accordance with ASTM D445–15 (titled “Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity)”), or as approved by FAA.

A38.4.2.2 Flight Test Procedures and Test Condition Stability. An applicant

must conduct each flight test in accordance with the flight test procedures and the stability conditions as follows:

A38.4.2.2.1 Flight Test Procedure.

The following procedures must be maintained during each flight used to gather data for determining SAR values:

A38.4.2.2.1.1 To the extent that is practicable, the airplane is flown at constant pressure altitude and constant heading along isobars;

A38.4.2.2.1.2 The engine thrust/power setting is stable for unaccelerated level flight;

A38.4.2.2.1.3 The airplane is flown as close as practicable to the reference specifications to minimize the magnitude of any correction;

A38.4.2.2.1.4 Changes in trim or engine power/thrust settings, engine stability and handling bleeds, or electrical and mechanical power extraction (including bleed flow) are avoided or minimized as practicable; and

A38.4.2.2.1.5 There is no unnecessary movement of on-board personnel.

A38.4.2.2.2 Test Condition Stability. To obtain a valid SAR measurement, the following conditions must be maintained during each test flight, including the indicated tolerances for at least 1 minute while SAR data is acquired:

A38.4.2.2.2.1 Mach number within ± 0.005 ;

A38.4.2.2.2.2 Ambient temperature within $\pm 1^\circ\text{C}$;
A38.4.2.2.2.3 Heading within ± 3 degrees;

A38.4.2.2.2.4 Track within ± 3 degrees;
A38.4.2.2.2.5 Drift angle less than 3 degrees;

A38.4.2.2.2.6 Ground speed within ± 3.7 km/h (± 2 kt);

A38.4.2.2.2.7 Difference in ground speed at the beginning of the SAR measurement from the ground speed at the end of the SAR measurement within ± 2.8 km/h/min (± 1.5 kt/min); and
A38.4.2.2.2.8 Pressure altitude within ± 23 m (± 75 ft).

A38.4.2.2.3 Alternatives to the stable test condition criteria of section A38.4.2.2.2 of this appendix may be used provided that stability is sufficiently demonstrated to the FAA.

A38.4.2.2.4 Data obtained at test points that do not meet the stability criteria of section A38.4.2.2.2 may be acceptable as an equivalent procedure, subject to FAA approval.

A38.4.2.2.5 SAR measurements at the test points must be separated by either:

A38.4.2.2.5.1 Two minutes; or

A38.4.2.2.5.2 An exceedance of one or more of the stability criteria limits described in A38.4.2.2.2.

A38.4.2.3 Verification of Airplane Mass at Test Conditions

A38.4.2.3.1 The procedure for determining the mass of the airplane at each test condition must be approved by the FAA.

A38.4.2.3.2 The mass of the airplane during a flight test is determined by subtracting the fuel used from the mass of the airplane at the start of the test flight. The accuracy of the determination of the fuel used must be verified by:

A38.4.2.3.2.1 Weighing the test airplane on calibrated scales before and after the SAR test flight;

A38.4.2.3.2.2 Weighing the test airplane before and after another test flight that included a cruise segment, provided that flight occurs within one week or 50 flight hours (at the option of the applicant) of the SAR test flight and using the same, unaltered fuel flow meters; or

A38.4.2.3.2.3 Other methods as approved by the FAA.

A38.5 Measurement of Specific Air Range

A38.5.1 Measurement System

A38.5.1.1 The following parameters must be recorded at a minimum sampling rate of 1 Hertz (cycle per second):

A38.5.1.1.1 Airspeed;

A38.5.1.1.2 Ground speed;

A38.5.1.1.3 True airspeed;

A38.5.1.1.4 Fuel flow;

A38.5.1.1.5 Engine power setting;

A38.5.1.1.6 Pressure altitude;

A38.5.1.1.7 Temperature;

A38.5.1.1.8 Heading;

A38.5.1.1.9 Track; and

A38.5.1.1.10 Fuel used (for the determination of gross mass and CG position).

A38.5.1.2 The following parameters must be recorded:

A38.5.1.2.1 Latitude;

A38.5.1.2.2 Engine bleed positions and power off-takes; and

A38.5.1.2.3 Power extraction (electrical and mechanical load).

A38.5.1.3 The value of each parameter used for the determination of SAR (except for ground speed) is the simple arithmetic average of the measured values for that parameter obtained throughout the stable test condition described in section A38.4.2.2.2 of this appendix.

A38.5.1.4 For ground speed, the value is the rate of change of ground speed during the SAR test measurement. The rate of change of ground speed during the SAR measurement must be used to evaluate and correct any acceleration or deceleration that might occur during the SAR measurement.

A38.5.1.5 Each measurement device must have sufficient resolution to determine that the stability of a parameter defined in section A38.4.2.2.2 of this appendix is maintained during SAR measurement.

A38.5.1.6 The SAR measurement system consists of the combined instruments and devices, and any associated procedures, used to acquire the following parameters necessary to determine SAR:

A38.5.1.6.1 Fuel flow;

A38.5.1.6.2 Mach number;

A38.5.1.6.3 Altitude;

A38.5.1.6.4 Airplane mass;

A38.5.1.6.5 Ground speed;

A38.5.1.6.6 Outside air temperature;

A38.5.1.6.7 Fuel lower heating value; and

A38.5.1.6.8 CG.

A38.5.1.7 The SAR value is affected by the accuracy of each element that comprises the SAR measurement system. The cumulative error associated with the SAR measurement system is defined as the root sum of squares (RSS) of the individual accuracies.

A38.5.1.8 If the absolute value of the cumulative error of the overall SAR measurement system is greater than 1.5 percent, a penalty equal to the amount that the RSS value exceeds 1.5 percent must be applied to the SAR value that has been corrected to reference specifications (see section A38.5.2 of this appendix). If the absolute value of

the cumulative error of the overall SAR measurement system is less than or equal to 1.5 percent, no penalty will be applied.

A38.5.2 Calculation of Specific Air Range from Measured Data

A38.5.2.1 Calculating SAR. SAR must be calculated using the following equation:

$$\text{SAR} = \text{TAS}/W_f$$

Where:

TAS is the true airspeed and W_f is total airplane fuel flow.

A38.5.2.2 Correcting Measured SAR Values to Reference Specifications

A38.5.2.2.1 The measured SAR values must be corrected to the reference specifications listed in A38.2 of this appendix. Unless otherwise approved by the FAA, corrections to reference specifications must be applied for each of the following measured parameters:

A38.5.2.2.1.1 *Acceleration/deceleration (energy)*. Drag determination is based on an assumption of steady, unaccelerated flight. Acceleration or deceleration occurring during a test condition affects the assessed drag level. The reference specification is in section A38.2.1.1.3 of this appendix.

A38.5.2.2.1.2 *Aeroelastics*. Wing aeroelasticity may cause a variation in drag as a function of airplane wing mass distribution. Airplane wing mass distribution will be affected by the fuel load distribution in the wings and the presence of any external stores. The reference specification is in section A38.2.1.1.7 of this appendix.

A38.5.2.2.1.3 *Altitude*. The altitude at which the airplane is flown affects the fuel flow. The reference specification is in section A38.2.1.1.2 of this appendix.

A38.5.2.2.1.4 *Apparent gravity*. Acceleration, caused by the local effect of gravity, and inertia, affect the test weight of the airplane. The apparent gravity at the test conditions varies with latitude, altitude, ground speed, and direction of motion relative to the Earth's axis. The reference gravitational acceleration is the gravitational acceleration for the airplane travelling in the direction of true North in still air at the reference altitude, a geodetic latitude of 45.5 degrees, and based on g_0 (see section A38.2.1.1.5 of this appendix).

A38.5.2.2.1.5 *CG position*. The position of the airplane CG affects the drag due to longitudinal trim. The reference specification is in section A38.2.1.1.6 of this appendix.

A38.5.2.2.1.6 *Electrical and mechanical power extraction and bleed flow*. Electrical and mechanical power extraction, and bleed flow affect the fuel

flow. The reference specifications are in sections A38.2.1.2.1 and A38.2.1.2.2 of this appendix.

A38.5.2.2.1.7 *Engine deterioration level.* The requirement in section A38.2.1.2.3 of this appendix addresses the minimum deterioration of an engine that is used to determine SAR. Since engine deterioration is rapid when an engine is new, when used for SAR determination:

A38.5.2.2.1.7.1 Subject to FAA approval, an engine having less deterioration than the reference deterioration level in section A38.2.1.2.3 of this appendix must correct the fuel flow to the reference deterioration using an approved method.

A38.5.2.2.1.7.2 An engine with greater deterioration than the reference deterioration level in section A38.2.1.2.3 of this appendix may be used, and no correction is permitted.

A38.5.2.2.1.8 *Fuel lower heating value.* The fuel lower heating value defines the energy content of the fuel. The lower heating value directly affects the fuel flow at a given test condition. The reference specification is in section A38.2.1.3.2 of this appendix.

A38.5.2.2.1.9 *Reynolds number.* The Reynolds number affects airplane drag. For a given test condition the Reynolds number is a function of the density and viscosity of air at the test altitude and temperature. The reference Reynolds number is derived from the density and viscosity of air from the ICAO standard atmosphere at the reference altitude (see sections A38.2.1.1.2 and A38.2.1.3.1 of this appendix, incorporated by reference see § 38.7).

A38.5.2.2.1.10 *Temperature.* The ambient temperature affects the fuel flow. The reference temperature is the standard day temperature from the ICAO standard atmosphere at the reference altitude (see section A38.2.1.3.1 of this appendix, incorporated by reference see § 38.7).

*Note 2 to A38.5.2.2.1.10—*Post-flight data analysis includes the correction of measured data for data acquisition hardware response characteristics (e.g., system latency, lag, offset, buffering, etc.).

A38.5.2.2.2 Correction methods are subject to the approval of the FAA.

A38.5.2.3 Using Specific Air Range to Determine the Fuel Efficiency Metric Value

A38.5.2.3.1 Calculate the SAR values for each of the three reference masses as described in § 38.13, including any corrections to reference specifications, as required under this part. The final SAR value for each reference mass is the simple arithmetic average of all valid

test points at the appropriate gross mass, or derived from a validated performance model. No data acquired from a valid test point may be omitted unless approved by the FAA.

A38.5.2.3.2 When an FAA-approved performance model is used, extrapolations to aircraft masses other than those tested may be approved when such extrapolations are consistent with accepted airworthiness practices. Since a performance model must be based on data covering an adequate range of lift coefficient, Mach number, and thrust specific fuel consumption, no extrapolation of those parameters is permitted.

A38.5.3 Validity of Results

A38.5.3.1 A 90 percent confidence interval must be calculated for each of the SAR values at the three reference masses.

A38.5.3.2 If the 90 percent confidence interval of the SAR value at any of the three reference airplane masses—

A38.5.3.2.1 Is less than or equal to ± 1.5 percent, the SAR value may be used.

A38.5.3.2.2 Exceeds ± 1.5 percent, a penalty equal to the amount that the 90 percent confidence interval exceeds ± 1.5 percent must be applied to the SAR value, as approved by the FAA.

A38.5.3.3 If clustered data is acquired separately for each of the three gross mass reference points, the minimum sample size acceptable for each of the three gross mass SAR values is six.

A38.5.3.4 If SAR data is collected over a range of masses, the minimum sample size is 12 and the 90 percent confidence interval is calculated for the mean regression line through the data.

A38.6 Submission of Certification Data to the FAA

The following information must be provided to the FAA in the certification reports for each airplane type and model for which fuel efficiency certification under this part is sought.

A38.6.1 General Information

A38.6.1.1 Designation of the airplane type and model:

A38.6.1.2 Configuration of the airplane, including CG range, number and type designation of engines and, if fitted, propellers, and any modifications or non-standard equipment expected to affect the fuel efficiency characteristics;

A38.6.1.3 MTOM used for certification under this part;

A38.6.1.4 All dimensions needed for calculation of RGF; and

A38.6.1.5 Serial number of each airplane used to establish fuel efficiency certification in accordance with this part.

A38.6.2 Reference Specifications. The reference specifications used to

determine any SAR value as described in section A38.2 of this appendix.

A38.6.3 Test Data. The following measured test data, including any corrections for instrumentation characteristics, must be provided for each of the test measurement points used to calculate the SAR values for each of the reference masses defined in § 38.13(b):

A38.6.3.1 Airspeed, ground speed and true airspeed;

A38.6.3.2 Fuel flow;

A38.6.3.3 Pressure altitude;

A38.6.3.4 Static air temperature;

A38.6.3.5 Airplane gross mass and CG for each test point;

A38.6.3.6 Levels of electrical and mechanical power extraction and bleed flow;

A38.6.3.7 Engine performance;

A38.6.3.7.1 For jet airplanes, engine power setting; or

A38.6.3.7.2 For propeller-driven airplanes, shaft horsepower or engine torque, and propeller rotational speed;

A38.6.3.8 Fuel lower heating value;

A38.6.3.9 When volumetric fuel flow meters are used, fuel specific gravity and kinematic viscosity (see section A38.4.2.1.5. of this appendix);

A38.6.3.10 The cumulative error (RSS) of the overall measurement system (see section A38.5.1.7 of this appendix);

A38.6.3.11 Heading, track and latitude;

A38.6.3.12 Stability criteria (see section A38.4.2.2.2 of this appendix); and

A38.6.3.13 Description of the instruments and devices used to acquire the data needed for the determination of SAR, and the individual accuracies of the equipment relevant to their effect on SAR (see sections A38.5.1.6 and A38.5.1.7 of this appendix).

A38.6.4 Calculations and Corrections of SAR Test Data to Reference Specifications. The measured SAR test data, all corrections of the measured data to the reference specifications, and the SAR values calculated from the corrected data must be provided for each of the test measurement points.

A38.6.5 Calculated Values. The following values must be provided for each airplane used to establish fuel efficiency certification in accordance with this part:

A38.6.5.1 SAR (km/kg) for each reference airplane mass and the associated 90 percent confidence interval;

A38.6.5.2 Average of the 1/SAR values;

A38.6.5.3 RGF; and

A38.6.5.4 Fuel efficiency metric value.

**PART 121—OPERATING
REQUIREMENTS: DOMESTIC, FLAG,
AND SUPPLEMENTAL OPERATIONS**

■ 13. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40119, 41706, 42301 preceding note added by Pub. L. 112–95, sec. 412, 126 Stat. 89, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44729, 44732; 46105; Pub. L. 111–216, 124 Stat. 2348 (49 U.S.C. 44701 note); Pub. L. 112–95 126 Stat 62 (49 U.S.C. 44732 note).

■ 14. Amend § 121.141 by revising paragraph (b) introductory text to read as follows:

§ 121.141 Airplane flight manual.

* * * * *

(b) In each airplane required to have an airplane flight manual in paragraph (a) of this section, the certificate holder shall carry either the manual required by § 121.133, if it contains the information required for the applicable flight manual and this information is clearly identified as flight manual requirements, or an approved Airplane Manual. If the certificate holder elects to

carry the manual required by § 121.133, the certificate holder may revise the operating procedures sections and modify the presentation of performance data, except for the information required by § 38.23 of this chapter identifying compliance with the fuel efficiency requirements of part 38 of this chapter, from the applicable flight manual if the revised operating procedures and modified performance data presentation are—

* * * * *

**PART 125—CERTIFICATION AND
OPERATIONS: AIRPLANES HAVING A
SEATING CAPACITY OF 20 OR MORE
PASSENGERS OR A MAXIMUM
PAYLOAD CAPACITY OF 6,000
POUNDS OR MORE; AND RULES
GOVERNING PERSONS ON BOARD
SUCH AIRCRAFT**

■ 15. The authority citation for part 125 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722.

■ 16. Amend § 125.75 by revising paragraph (b) to read as follows:

§ 125.75 Airplane flight manual.

* * * * *

(b) Each certificate holder shall carry the approved Airplane Flight Manual or the approved equivalent aboard each airplane it operates. A certificate holder may elect to carry a combination of the manuals required by this section and § 125.71. If it so elects, the certificate holder may revise the operating procedures sections and modify the presentation of performance from the applicable Airplane Flight Manual if the revised operating procedures and modified performance data presentation are approved by the Administrator. Any approved equivalent must include the information required by § 38.23 of this chapter identifying compliance with the fuel efficiency requirements of part 38 of this chapter.

Issued under authority provided in 42 U.S.C. 4321 *et seq.*, 7572, 49 U.S.C. 106(f), 40133, 44701–44701, 44703, and 44704 in Washington, DC.

Michael Gordon Whitaker,
Administrator.

[FR Doc. 2024–02330 Filed 2–15–24; 8:45 am]

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Part V

Environmental Protection Agency

40 CFR Parts 52 and 97

Supplemental Air Plan Actions: Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards and Supplemental Federal “Good Neighbor Plan” Requirements for the 2015 8-Hour Ozone National Ambient Air Quality Standards; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 97

[EPA-HQ-OAR-2021-0663; EPA-HQ-OAR-2021-0668; EPA-HQ-OAR-2023-0402; FRL-11159-01-OAR]

RIN 2060-AW09

Supplemental Air Plan Actions: Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards and Supplemental Federal "Good Neighbor Plan" Requirements for the 2015 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; supplemental proposed rule and withdrawal of proposed rules.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to partially disapprove and partially approve State Implementation Plan (SIP) submissions from Arizona, Iowa, Kansas, New Mexico, and Tennessee regarding interstate transport for the 2015 8-hour ozone national ambient air quality standards (NAAQS). This action also proposes a Federal Implementation Plan (FIP) for Arizona, Iowa, Kansas, New Mexico, and Tennessee to address these States' obligations to eliminate significant contribution to nonattainment, or interference with maintenance, of the 2015 ozone NAAQS in other states. The FIP would require fossil fuel-fired power plants in the five states to participate in an allowance-based ozone season nitrogen oxides emissions trading program beginning in 2025. The Agency is also proposing to establish nitrogen oxides emissions limitations applicable to certain other industrial stationary sources in Arizona with a compliance year no earlier than 2027. Finally, this action also includes proposed technical corrections to the regulatory text previously promulgated to establish comparable FIP requirements for emissions sources in other states.

DATES:

Comments: Comments must be received on or before May 16, 2024.

Public hearing: The EPA will hold a virtual public hearing on March 4, 2024. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

Information collection request: Under the Paperwork Reduction Act (PRA),

comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before March 18, 2024.

ADDRESSES:

Comments: You may send comments, identified as Docket ID No. EPA-HQ-OAR-2023-0402, by any of the following methods: Federal eRulemaking Portal: <https://www.regulations.gov/>. Follow the online instructions for submitting comments. Include Docket ID No. EPA-HQ-OAR-2023-0402 in the subject line of the message.

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 "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Hearing: The virtual hearing will be held at <https://www.epa.gov/csapr/csapr-2015-ozone-naaqs>. The public hearing will convene at 9:00 a.m. and end at 6:00 p.m. Eastern Time (ET) or 1 hour after the last registered speaker has spoken. The EPA will make every effort to accommodate all individuals interested in providing oral testimony. A lunch break is scheduled from 12:00 p.m. until 1:00 p.m. Refer to the **SUPPLEMENTARY INFORMATION** section for additional information.

FOR FURTHER INFORMATION CONTACT:

Thomas Uher, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539-04), Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, NC 27711; telephone number: (919) 541-5534; email address: uher.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

Public participation: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2023-0402, at <https://www.regulations.gov/> (our preferred method). Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the 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. 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).

There are three dockets supporting this action, EPA-HQ-OAR-2023-0402, EPA-HQ-OAR-2021-0663, and EPA-HQ-OAR-2021-0668. All comments regarding information in any of these dockets are to be made in Docket ID No. EPA-HQ-OAR-2023-0402.

The index to the docket for this action, Docket ID No. EPA-HQ-OAR-2023-0402, is available electronically at <https://www.regulations.gov/>. While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.*, CBI).

Preamble Glossary of Terms and Abbreviations

The following are abbreviations of terms used in the preamble.

2016v1 2016 Version 1 Emissions Modeling Platform
 2016v2 2016 Version 2 Emissions Modeling Platform
 2016v3 2016 Version 3 Emissions Modeling Platform
 ARP Acid Rain Program
 ADEQ Arizona Department of Environmental Quality
 CAA or Act Clean Air Act
 CAIR Clean Air Interstate Rule
 CBI Confidential Business Information
 CFB Circulating Fluidized Bed Units
 CFR Code of Federal Regulations
 CSAPR Cross-State Air Pollution Rule
 DAHS Data Acquisition and Handling System
 EAV Equivalent Annualized Values
 EGU Electric Generating Unit
 EHD Environmental Health Department
 EIA Economic Impact Assessment
 EPA or the Agency United States Environmental Protection Agency
 FIP Federal Implementation Plan
 g/hp-hr Grams per horsepower per hour
 Group 2 allowances CSAPR NO_x Ozone Season Group 2 allowances
 Group 2 trading program CSAPR NO_x Ozone Season Group 2 Trading Program
 Group 3 allowances CSAPR NO_x Ozone Season Group 3 allowances
 Group 3 Trading Program CSAPR NO_x Ozone Season Group 3 Trading Program
 ICR Information Collection Request
 IPM Integrated Planning Model
 LNB Low-NO_x Burners
 MJO Multi-Jurisdictional Organization
 MOVES Motor Vehicle Emission Simulator
 MW Megawatts
 NAA Nonattainment Area
 NAAQS National Ambient Air Quality Standards
 NAICS North American Industry Classification System

NMED New Mexico Environment Department
 Non-EGU Non-Electric Generating Unit
 NODA Notice of Data Availability
 NO_x Nitrogen Oxides
 NSCR Non-Selective Catalytic Reduction
 OMB United States Office of Management and Budget
 PBI Proprietary Business Information
 ppb parts per billion
 ppm parts per million
 ppmvd parts per million by volume, dry
 PRA Paperwork Reduction Act
 PV Present Value
 RFA Regulatory Flexibility Act
 RIA Regulatory Impact Analysis
 RICE Reciprocating Internal Combustion Engines
 SC-CO₂ Social Cost of Carbon
 SCR Selective Catalytic Reduction
 SIL Significant Impact Level
 SIP State Implementation Plan
 SNCR Selective Non-Catalytic Reduction
 SO₂ Sulfur Dioxide
 TAS Treatment as State
 TDEC Tennessee Department of Environmental Control
 TSD Technical Support Document
 tpy tons per year
 UMRA Unfunded Mandates Reform Act
 Violating-Monitor Receptors Violating-Monitor Maintenance-Only Receptors
 VOCs Volatile Organic Compounds

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I. Executive Summary

This proposed rule would resolve the interstate transport obligations of five states under CAA section 110(a)(2)(D)(i)(I), referred to as the

“good neighbor provision” or the “interstate transport provision” of the Act, for the 2015 ozone NAAQS. On October 1, 2015, the EPA revised the primary and secondary 8-hour standards for ozone to 70 parts per billion (ppb).¹ States were required to provide ozone infrastructure SIP submissions to fulfill interstate transport obligations for the 2015 ozone NAAQS by October 1, 2018.

The EPA proposes to make a finding that interstate transport of ozone precursor emissions from five upwind states (Arizona, Iowa, Kansas, New Mexico, and Tennessee) is interfering with maintenance of the 2015 ozone NAAQS in other states. The EPA is withdrawing its previous proposed actions on SIP submissions from Arizona and Tennessee,² proposing to partially approve and partially disapprove good neighbor SIP submissions from Arizona, New Mexico, and Tennessee, and to error-correct its prior good neighbor SIP approval actions for Iowa and Kansas to partial disapprovals.³ To fulfill the EPA’s responsibility to ensure that states meet their interstate transport obligations as expeditiously as practicable to meet attainment deadlines for the 2015 ozone NAAQS, the EPA also proposes FIP requirements for these five states to prohibit the emissions that interfere with maintenance of the NAAQS in other states. For states covered in this action, the EPA proposes to define new ozone season nitrogen oxides (NO_x) emissions performance obligations for Electric Generating Unit (EGU) sources and to fulfill those obligations by implementing an allowance-based ozone season trading program beginning in 2025. The EPA is also proposing to establish emissions limitations beginning in 2027 for certain other industrial stationary sources (referred to generally as “non-Electric Generating Units” or non-EGUs) in Arizona. Taken together, these strategies will fully resolve the covered states’ good neighbor obligations for the 2015 ozone NAAQS.

The EPA proposes to implement the necessary emissions reductions as follows. The proposed FIP requirements establish ozone season NO_x emissions budgets for EGUs in Arizona, Iowa, Kansas, New Mexico, and Tennessee and require EGUs in these states to participate in the revised version of the Cross-State Air Pollution Rule (CSAPR)

NO_x Ozone Season Group 3 Trading Program established in the final Federal Good Neighbor Plan Rule.⁴ For states currently covered by the CSAPR NO_x Ozone Season Group 2 Trading Program (*i.e.*, Iowa, Kansas, Tennessee), the EPA proposes to amend existing FIPs to transition EGU sources in these states from the Group 2 trading program to the revised Group 3 trading program, beginning with the 2025 ozone season. The EPA proposes to issue new FIPs for Arizona and New Mexico, which are not currently covered by any CSAPR NO_x ozone season trading program. Under CAA section 301(d)(4), the EPA also proposes to extend the FIP requirements to apply in Indian country located within the geographical boundaries of the states included in this proposal, including Indian reservation lands and other areas of Indian country over which the EPA or a tribe has demonstrated that a tribe has jurisdiction.

The timeframes for implementation of these emissions-reduction strategies are, in the EPA’s judgment, as expeditious as practicable and aligned to the extent possible with the attainment schedule for downwind areas in nonattainment of the 2015 ozone NAAQS. As discussed in section VI. of this document, the EPA proposes to find that the 2025 ozone season is as expeditious as practicable to implement emissions reductions associated with near-term emissions control strategies at EGUs, and the 2027 ozone season is as expeditious as practicable to implement emissions reductions associated with new post-combustion control installations at EGUs as well as from installation of new pollution controls at non-EGUs.

As identified in section VI. of this document, the EPA proposes to find that, because Iowa, Kansas, New Mexico, and Tennessee are not linked to receptors in the 2026 ozone season, the near-term EGU emissions-control strategy is sufficient to eliminate these states’ interference with maintenance of the NAAQS in other states. Because Arizona remains linked to receptors through the 2026 ozone season, the EPA proposes to find that additional NO_x emissions from EGUs and NO_x emissions from non-EGU sources in Arizona are interfering with maintenance of the 2015 ozone NAAQS in other states and that additional cost-effective controls for NO_x emissions reductions are available from EGUs and in certain industries that would result in meaningful air quality improvements at

downwind receptors. Thus, in addition to more stringent EGU emissions budgets for Arizona beginning in 2027, the EPA proposes to require emissions limitations beginning in 2027 for non-EGUs located within Arizona. The Federal Good Neighbor Plan established NO_x emissions limitations during the ozone season for the following unit types for sources in non-EGU industries: reciprocating internal combustion engines (RICE) in Pipeline Transportation of Natural Gas; kilns in Cement and Cement Product Manufacturing; boilers and rehear furnaces in Iron and Steel Mills and Ferroalloy Manufacturing; furnaces in Glass and Glass Product Manufacturing; boilers in Basic Chemical Manufacturing, Metal Ore Mining, Petroleum and Coal Products Manufacturing, and Pulp, Paper, and Paperboard Mills and combustors and incinerators in Solid Waste Combustors and Incinerators.⁵

A. Purpose of the Regulatory Action

In this supplemental notice of proposed rulemaking, the EPA is providing an opportunity for public comment on its proposed conclusion that SIP submissions from Arizona, New Mexico, and Tennessee do not contain the necessary provisions to prohibit emissions from sources within their states from interfering with maintenance of the 2015 ozone NAAQS in downwind areas. The EPA also proposes to find it necessary to issue an error correction under the authority of CAA section 110(k)(6) of its previous approval actions for Kansas and Iowa and proposes to partially disapprove these states’ interstate transport submissions. In addition, the EPA proposes to conclude that emissions from sources in Arizona, Iowa, Kansas, New Mexico, and Tennessee interfere with maintenance of the 2015 ozone NAAQS in other states, and therefore the EPA is proposing FIPs to address these states’ transport obligations through expanding the coverage of the Federal Good Neighbor Plan Rule⁶ finalized on March 15, 2023. The EPA is proposing to implement the ozone season NO_x trading program requirements for EGU sources in the Federal Good Neighbor Plan as the FIPs for Arizona, Iowa, Kansas, New Mexico, and Tennessee and the emissions limits for non-EGU (industrial) sources in the Federal Good Neighbor Plan as the FIP for Arizona. These control strategies, if finalized,

¹ See 80 FR 65291 (October 26, 2015).

² See 87 FR 37776 (June 24, 2022). (The EPA’s proposed approval of Arizona’s SIP); and 87 FR 9545 (February 22, 2022) (The EPA’s proposed disapproval of Tennessee’s SIP).

³ See 87 FR 22463 (April 15, 2022) (Iowa); and 87 FR 19390 (April 4, 2022) (Kansas).

⁴ Federal “Good Neighbor Plan” for the 2015 Ozone National Ambient Air Quality Standards, 88 FR 36654 (June 5, 2023).

⁵ 88 FR 36654, at 36817.

⁶ Federal “Good Neighbor Plan” for the 2015 Ozone National Ambient Air Quality Standards, 88 FR 36654 (June 5, 2023).

will prohibit the emissions from these five states identified as interfering with maintenance of the 2015 ozone NAAQS in other states.

The EPA proposes to extend the coverage of the Federal Good Neighbor Plan to these five additional states based on the same data and analyses contained in that rule. In the Federal Good Neighbor Plan, the EPA identified and finalized FIPs for 23 states with emissions that significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in other states. The EPA used the same set of nationwide air quality modeling, air quality monitoring data, and technical analysis of emissions control opportunities in defining good neighbor obligations for all states covered in that action. Consistent with the application of the EPA's 4-step interstate transport framework, which has been used in prior good neighbor rules like the CSAPR and upheld by the federal courts, the EPA applied emissions control requirements on a uniform basis across those states based on that record.

The EPA maintains that it is reasonable, appropriate, and consistent with the EPA's prior decisions to extend the Federal Good Neighbor Plan's contribution analysis and emissions control requirements to include the five states covered in this action. The EPA has not identified any factors unique to these five states that would warrant applying a different approach. These five states were not addressed in the Federal Good Neighbor Plan because the EPA was not positioned to take final rulemaking action to disapprove SIPs, error correct prior approvals to disapprovals, or promulgate FIPs for these states at that time. To maintain consistency across all states such that the allocation of responsibility for eliminating states' significant contribution and interference with maintenance of the NAAQS in downwind states is done on an equitable basis, the EPA proposes to apply to five additional states the nationwide findings and determinations contained in the Federal Good Neighbor Plan as to the original 23 states which will, if finalized, eliminate these additional states' significant contribution. Thus, in this action the EPA proposes to apply to these five states its air quality modeling and contribution information for the analytical years 2023 and 2026 at Steps 1 and 2, its analysis of emissions control opportunities for EGUs and non-EGUs and determinations of stringency, including overcontrol analysis, at Step 3, and its implementation programs at Step 4. The technical materials and

record-based findings that underlie these determinations are all contained in the Federal Good Neighbor Plan record. The scope of this rulemaking is limited to the application of that record to these five additional states.

Thus, in this document, the EPA is taking comment only on (a) the EPA's proposed conclusions that SIP submissions from Arizona, New Mexico, and Tennessee do not contain the necessary provisions to prohibit emissions from sources within their respective states from interfering with maintenance of the 2015 ozone standard, (b) the EPA's proposed conclusion that the Agency must error correct its final rules approving SIPs from Iowa and Kansas to partial disapprovals, (c) the EPA's proposed conclusions that the five states identified above have emissions that interfere with maintenance of the 2015 ozone NAAQS in other states, and (d) the EPA's proposed decision to apply the Federal Good Neighbor Plan emissions-control programs as the FIP requirements to address these emissions in these five states.

Additionally, the EPA has updated its analysis of air quality improvements at Step 3 and demonstration that there is no overcontrol resulting from the inclusion of these five additional states in the Federal Good Neighbor Plan. The EPA proposes that the 2025 and 2027 ozone seasons represent appropriate compliance start-dates for these states, affording sufficient lead time for sources to plan for compliance from the standpoint of when this rulemaking will likely be finalized, which the EPA currently anticipates will be in the summer of 2024. These proposed findings are within the scope of this rulemaking and open for public comment.

The EPA is not reopening any determinations made in the Federal Good Neighbor Plan as to the 23 states covered in that action. Nor is the EPA taking comment on any aspect of the Federal Good Neighbor Plan, except to the extent of its application to these five states. In general, the record for the Federal Good Neighbor Plan Rule contains information at each step of the 4-step interstate transport framework that can be applied to these five states. Thus, the identification of receptors to which these five states are linked and the level of contribution from these states to those receptors is based on the same analytical findings using the air quality modeling and monitoring data contained in the Federal Good Neighbor Plan. In addition, the analysis underlying the EPA's determinations at Step 3 as to EGUs and non-EGUs and

the appropriate degree of emissions-control stringency needed to eliminate significant contribution and interference with maintenance likewise was conducted on a region-wide basis, and in the EPA's view is reasonably applied to the emissions sources in these five states. The emissions-control requirements were established on a uniform basis for each particular industry covered in the Federal Good Neighbor Plan, and do not vary by State (except to the extent that states not linked in 2026 are not subject to the requirements that onset in 2026 and California's EGUs are not subject to the EGU trading program). Based on these findings, these programs should be extended to these five states. This is reasonable and indeed necessary to ensure consistency and equitable treatment across all states in addressing the nationwide problem of interstate ozone pollution for the 2015 ozone NAAQS. *See EME Homer City v. EPA*, 472 U.S. 572, 519, 524 (2014). This is also consistent with the EPA's practice throughout the history of implementing the good neighbor provision for other NAAQS. For instance, using the final analysis in the original CSAPR rulemaking, the EPA soon after conducted rulemaking to include five additional states in the CSAPR trading programs. *See* 76 FR 80760 (December 27, 2011). Thus, for the same reasons, the EPA proposes to find it reasonable and appropriate to extend the uniform set of findings and determinations made in the Federal Good Neighbor Plan to these five additional states for the 2015 ozone NAAQS. The EPA is not aware of any information with respect to these states that would justify a deviation from the same set of findings and requirements that already have been made for the 23 states covered in the Federal Good Neighbor Plan with respect to these same obligations.

Finally, this action also includes proposed technical corrections to the existing regulatory text finalized in the Federal Good Neighbor Plan.

B. Costs and Benefits

Table I.B–1 summarizes the key results of the cost-benefit analysis that was prepared for this proposed rule. Table I.B–1 presents estimates of the present values (PV) and equivalent annualized values (EAV), calculated using discount rates of 3 and 7 percent as recommended by the Office of Management and Budget's (OMB) Circular A–4, of the health and climate benefits, compliance costs, and net benefits of the proposed rule, in 2016 dollars, discounted to 2023. The estimated monetized net benefits are the

estimated monetized benefits minus the estimated monetized costs of the proposed rule. These results present an incomplete overview of the effects of the rule because important categories of

benefits were not monetized (e.g., ecosystem effects, visibility impairment, and water quality improvements) and are therefore not reflected in the cost-benefit tables. The EPA anticipates that

taking non-monetized effects into account would show the proposed rule to be more net beneficial than this table reflects.

TABLE I.B–1—ESTIMATED MONETIZED HEALTH AND CLIMATE BENEFITS, COMPLIANCE COSTS, AND NET BENEFITS OF THE PROPOSED RULE, 2025 THROUGH 2044

[Millions 2016\$, discounted to 2023]^a

	3% Discount rate	7% Discount rate
Present Value:		
Health Benefits ^b	\$330 and \$1,900	\$210 and \$1,200.
Climate Benefits ^c	\$9.3	\$9.3.
Compliance Costs ^d	\$67	\$45.
Net Benefits	\$270 and \$1,800	\$180 and \$1,100.
Equivalent Annualized Value:		
Health Benefits	\$22 and \$130	\$20 and \$110.
Climate Benefits	\$0.6	\$0.6.
Compliance Costs	\$4.5	\$4.2.
Net Benefits	\$18 and \$120	\$17 and \$110.

^a Rows may not appear to add correctly due to rounding. The EPA used 2016 dollars in both the proposal and final Revised CSAPR Update Regulatory Impact Analysis (RIA), as well as the proposal and final Federal Good Neighbor Plan RIA; to be consistent with those recent actions we continued to use 2016 dollars as the dollar year for presenting costs and benefits.

^b The annualized present value of costs and benefits are calculated over a 20-year period from 2025 to 2044. Monetized benefits include those related to public health associated with reductions in ozone and PM_{2.5} concentrations. The health benefits are associated with two alternative estimates of the number of premature deaths and are presented at real discount rates of 3 and 7 percent. Several categories of benefits remain unmonetized and are thus not reflected in the table.

^c Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO₂) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). For presentational purposes in this table, the climate benefits associated with the average SC-CO₂ at a 3-percent discount rate are used in the columns displaying results of other costs and benefits that are discounted at either a 3-percent or 7-percent discount rate.

^d The costs presented in this table are consistent with the costs presented in section 3 of the *Economic Impact Assessment (EIA)*. To estimate these annualized costs for EGUs, the EPA uses a conventional and widely accepted approach that applies a capital recovery factor multiplier to capital investments and adds that to the annual incremental operating expenses. Costs were calculated using a 3.75 percent real discount rate consistent with the rate used in the Integrated Planning Model's (IPM) objective function for cost-minimization. For further information on the discount rate use, please see section 3 of the *EIA*.

As shown in Table I.B–1, the PV of the monetized health benefits, associated with reductions in ozone and PM_{2.5} of this proposed rule, discounted at a 3-percent discount rate, is estimated to be about \$330 and \$1,900 million, with an EAV of about \$22 and \$130 million. At a 7-percent discount rate, the PV of the monetized health benefits is estimated to be \$210 and \$1,200 million, with an EAV of about \$20 and \$110 million. The PV of the monetized

climate benefits, associated with reductions in greenhouse gas (GHG) emissions, of this proposed rule, discounted at a 3-percent discount rate, is estimated to be about \$9.3 million, with an EAV of about \$0.6 million. The PV of the monetized compliance costs, discounted at a 3-percent rate, is estimated to be about \$67 million, with an EAV of about \$4.5 million. At a 7-percent discount rate, the PV of the compliance costs is estimated to be

about \$45 million, with an EAV of about \$4.2 million.

II. General Information

A. Does this action apply to me?

This supplemental proposed rule affects EGU and non-EGU sources, and regulates the groups identified in Table II.A–1, along with their North American Industry Classification System (NAICS) code.

TABLE II.A–1—REGULATED GROUPS

Industry group	NAICS
Fossil fuel-fired electric power generation	221112
Pipeline Transportation of Natural Gas	4862
Metal Ore Mining	2122
Cement and Concrete Product Manufacturing	3273
Iron and Steel Mills and Ferroalloy Manufacturing	3311
Glass and Glass Product Manufacturing	3272
Basic Chemical Manufacturing	3251
Petroleum and Coal Products Manufacturing	3241
Pulp, Paper, and Paperboard Mills	3221
Solid Waste Combustors and Incinerators	562213

This table is not intended to be exhaustive, but rather provides a guide

for readers regarding entities likely to be regulated by this proposed rule. This

table lists the types of entities that the EPA is now aware could potentially be

regulated by this proposed rule. Other types of entities not listed in the table could also be regulated. To determine whether a particular entity is regulated by this proposed rule, you should carefully examine the applicability criteria found in 40 CFR 97.1004 (EGUs) or 40 CFR 52.40(c), 52.41(b), 52.42(b), 52.43(b), 52.44(b), 52.45(b), and 52.46(b) (non-EGUs). If you have questions regarding the applicability of this proposed rule to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

The EPA evaluated whether interstate ozone transport emissions from upwind states are significantly contributing to nonattainment, or interfering with maintenance, of the 2015 ozone NAAQS in any downwind State using the same 4-step interstate transport framework that was developed in previous ozone transport rulemakings. In its previous action, the Federal Good Neighbor Plan, the EPA found that sources in 23 states had obligations to eliminate their significant contribution to nonattainment and interference with maintenance in downwind areas.⁷ In this proposed rule, the EPA is proposing to apply that same analysis to find that emissions reductions are required from EGU sources in the additional states of Arizona, Iowa, Kansas, New Mexico, and Tennessee and from non-EGU sources in Arizona. The EPA proposes to ensure that these NO_x emissions reductions are achieved by issuing FIP requirements for these five states.

In this rule, the EPA is proposing to find that SIP submissions from Arizona, New Mexico, and Tennessee lack adequate provisions to ensure sources and other emissions activity in their states are not interfering with maintenance of the 2015 ozone NAAQS in other states. The EPA is also proposing to error correct its previous actions on SIP submissions from Iowa and Kansas to partial disapprovals for the same reason.⁸

In this same action, the EPA proposes FIP requirements for these five states. The EPA is proposing to incorporate Arizona, Iowa, Kansas, New Mexico, and Tennessee into the existing CSAPR NO_x Ozone Season Group 3 Trading Program established in the Federal Good Neighbor Plan, beginning in the 2025 ozone season. EGUs in states not currently covered by any CSAPR trading program for seasonal NO_x emissions—Arizona and New Mexico—will be

added to the CSAPR NO_x Ozone Season Group 3 Trading Program under this rule. EGUs in Iowa, Kansas, and Tennessee will transition from the CSAPR NO_x Ozone Season Group 2 Trading Program to the CSAPR NO_x Ozone Season Group 3 Trading Program. The EPA is establishing a control stringency level reflecting optimization of existing post-combustion controls and installation of state-of-the-art combustion controls on certain covered EGU sources in the emissions budgets beginning in the 2025 ozone season. In addition, for Arizona, the EPA is establishing a control stringency level reflecting installation of new Selective Catalytic Reduction (SCR) or Selective Non-Catalytic Reduction (SNCR) controls on certain covered EGU sources in its emissions budgets beginning with the 2027 ozone season.

Consistent with the emissions limitations established for non-EGU sources in the Federal Good Neighbor Plan, this supplemental action proposes to establish emissions limitations for new and existing non-EGU sources in Arizona beginning with the 2027 ozone season. The Federal Good Neighbor Plan established control requirements for the following unit types in non-EGU industries: RICE in Pipeline Transportation of Natural Gas; kilns in Cement and Cement Product Manufacturing; reheat furnaces in Iron and Steel Mills and Ferroalloy Manufacturing; furnaces in Glass and Glass Product Manufacturing; boilers in Iron and Steel Mills and Ferroalloy Manufacturing, Metal Ore Mining, Basic Chemical Manufacturing, Petroleum and Coal Products Manufacturing, and Pulp, Paper, and Paperboard Mills; and combustors and incinerators in Solid Waste Combustors and Incinerators. See Table II.A–1 in this document for a list of NAICS codes for the relevant industries.

In accordance with the requirements of the good neighbor provision, CAA section 110(a)(2)(D)(i)(I), this proposed rule reduces the transport of ozone and ozone precursors from emissions in upwind states to downwind areas to protect human health and the environment from negative health impacts associated with acute and chronic exposure to ozone. Ozone exposure is also associated with negative effects on ecosystems. Additional information on the air quality issues addressed by this proposed rule is included in section IX. of this document.

C. What is the Agency's authority for taking this action?

The statutory authority for this proposed action is provided by the CAA as amended (42 U.S.C. 7401 *et seq.*). Specifically, sections 110 and 301 of the CAA provide the primary statutory underpinnings for this action. The most relevant portions of CAA section 110 are subsections 110(a)(1), 110(a)(2) (including 110(a)(2)(D)(i)(I)), 110(k)(2), 110(k)(3), 110(k)(6), and 110(c)(1).

CAA section 110(a)(1) provides that states must make SIP submissions “within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),” and that these SIP submissions are to provide for the “implementation, maintenance, and enforcement” of such NAAQS.⁹ The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon the EPA taking any action other than promulgating a new or revised NAAQS.¹⁰

The EPA has historically referred to SIP submissions made for the purpose of satisfying the applicable requirements of CAA sections 110(a)(1) and 110(a)(2) as “infrastructure SIP” or “iSIP” submissions.” CAA section 110(a)(1) addresses the timing and general requirements for iSIP submissions, and CAA section 110(a)(2) provides more details concerning the required content of these submissions.¹¹ It includes a list of specific elements that “[e]ach such plan” must address, including the requirements of the good neighbor provision.¹²

CAA section 110(c)(1) requires the Administrator to promulgate a FIP at any time within 2 years after the Administrator: (1) finds that a State has failed to make a required SIP submission; (2) finds a SIP submission to be incomplete pursuant to CAA section 110(k)(1)(C); or (3) disapproves a SIP submission. This obligation applies unless the State corrects the deficiency through a SIP revision that

⁹ 42 U.S.C. 7410(a)(1).

¹⁰ See *EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 509–10 (2014).

¹¹ 42 U.S.C. 7410(a)(2).

¹² The EPA's general approach to infrastructure SIP submissions is explained in greater detail in individual documents acting or proposing to act on State infrastructure SIP submissions and in guidance. See, e.g., Memorandum from Stephen D. Page on Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2) (September 13, 2013).

⁷ 88 FR 36654 (June 5, 2023).

⁸ 87 FR 22463 (April 15, 2022) (Iowa); 87 FR 19390 (April 4, 2022) (Kansas).

the Administrator approves before the FIP is promulgated.¹³

CAA section 110(a)(2)(D)(i)(I), also known as the “good neighbor” provision, provides the primary basis for this proposed action.¹⁴ It requires that each State’s SIP include provisions sufficient to “prohibit[], consistent with the provisions of this subchapter, any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will—(I) contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any [NAAQS].”¹⁵ The EPA often refers to the emissions reduction requirements under this provision as “good neighbor obligations” and submissions addressing these requirements as “good neighbor SIPs.”

Once the EPA promulgates a NAAQS, the EPA must designate areas as being in “attainment” or “nonattainment” of the NAAQS, or “unclassifiable.” CAA section 107(d).¹⁶ For ozone, nonattainment is further split into five classifications based on the severity of the violation—Marginal, Moderate, Serious, Severe, or Extreme. Higher classifications provide states with progressively more time to attain while imposing progressively more stringent control requirements. See CAA sections 181, 182.¹⁷ In general, states with nonattainment areas classified as Moderate or higher must submit plans to the EPA to bring these areas into attainment according to the statutory schedule in CAA section 182.¹⁸ If an area fails to attain the NAAQS by the attainment date associated with its classification, it is “bumped up” to the next classification, per the requirements in CAA section 181(b).¹⁹

Section 301(a)(1) of the CAA gives the Administrator the general authority to prescribe such regulations as are necessary to carry out functions under the Act.²⁰ Pursuant to this section, the EPA has authority to clarify the applicability of CAA requirements and undertake other rulemaking action as necessary to implement CAA requirements. CAA section 301 affords the Agency any additional authority that may be needed to make certain other changes to its regulations under 40 CFR parts 52 and 97 to effectuate the purposes of the Act. Such changes are

discussed in section X. of this document.

Section 110(k)(6) of the CAA gives the Administrator authority, without any further submission from a state, to revise certain prior actions, including actions to approve SIP submissions, upon determining that those actions were in error.²¹ As discussed further in section V.A. of this document, the EPA proposes to make error corrections under CAA section 110(k)(6) with respect to its prior approvals of the 2015 ozone transport SIP submissions from the States of Iowa and Kansas.

Tribes are not required to submit State implementation plans. However, as explained in the EPA’s regulations outlining Tribal CAA authority, the EPA is authorized to promulgate FIPs for Indian country as necessary or appropriate to protect air quality if a Tribe does not submit, and obtain the EPA’s approval of, an implementation plan. See 40 CFR 49.11(a); see also CAA section 301(d)(4).²² In this action, the EPA proposes an “appropriate or necessary” finding under CAA section 301(d) and proposes Tribal FIP(s) as necessary to implement the relevant requirements. This is further discussed in section V.B. of this document.

D. Severability

The EPA regards this proposal as a complete remedy for the covered states, which will as expeditiously as practicable implement good neighbor obligations for the 2015 ozone NAAQS, consistent with the requirements of the Act. See *North Carolina v. EPA*, 531 F.3d 896, 911–12 (D.C. Cir. 2008); *Wisconsin v. EPA*, 938 F.3d 303, 313–20 (D.C. Cir. 2019); *Maryland v. EPA*, 958 F.3d 1185, 1204 (D.C. Cir. 2020); *New York v. EPA*, 964 F.3d 1214, 1226 (D.C. Cir. 2020); *New York v. EPA*, 781 Fed. App’x 4, 7–8 (D.C. Cir. 2019) (all holding that the EPA must address good neighbor obligations as expeditiously as practicable and by no later than the next applicable attainment date). Yet the EPA proposes that should a court find any discrete aspect of this action, if finalized, to be invalid, the Agency believes that, like the Federal Good Neighbor Plan, the remaining aspects of this proposed rule can and should continue to be implemented to the extent possible, consistent with law. See 88 FR 36693. In particular, this proposal would disapprove SIP submissions and promulgate a FIP for each covered state (and, pursuant to CAA section 301(d), for each area of tribal jurisdiction within the geographic boundaries of those

states). Should any jurisdiction-specific aspect of the rule, once finalized be found invalid, the EPA views this rule, if finalized as proposed, as severable along those state and/or tribal jurisdictional lines, such that the proposed rule could continue to be implemented as to any remaining jurisdictions. This action proposes discrete emissions control requirements for the power sector and for each of nine other industries. Should any industry-specific aspect of the proposed rule be found invalid once final, the EPA views this rule as proposed as severable as between the different industries and different types of emissions control requirements. This is not intended to be an exhaustive list of the ways in which the proposed rule may be severable. In the event any part of the rule, if finalized, is found invalid, our intention is that the remaining portions should continue to be implemented consistent with any judicial ruling.²³

The EPA’s conclusion that this proposed rule, upon finalization, is severable also reflects the important public health and environmental benefits of this rulemaking in eliminating significant contribution and to ensure to the greatest extent possible the ability of both upwind states and downwind states and other relevant stakeholders to be able to rely on this rule at final in their planning. Cf. *Wisconsin*, 938 F.3d at 336–37 (“As a general rule, we do not vacate regulations when doing so would risk significant harm to the public health or the environment.”); *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008) (noting the need to preserve public health benefits); *EME Homer City v. EPA*, 795 F.3d 118, 132 (D.C. Cir. 2015) (noting the need to avoid disruption to emissions trading market that had developed).

E. Public Participation

1. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2023–0402, at <https://www.regulations.gov>. Once submitted, comments cannot be

¹³ 42 U.S.C. 7410(c)(1).

¹⁴ 42 U.S.C. 7410(a)(2)(D)(i)(I).

¹⁵ *Id.*

¹⁶ 42 U.S.C. 7407(d).

¹⁷ 42 U.S.C. 7511, 7511a.

¹⁸ 42 U.S.C. 7511a.

¹⁹ 42 U.S.C. 7511(b).

²⁰ 42 U.S.C. 7601(a)(1).

²¹ 42 U.S.C. 7410(k)(6).

²² 42 U.S.C. 7601(d)(4).

²³ In a declaration dated October 28, 2023, and filed with the U.S. Supreme Court in *State of Ohio et al. v. EPA*, No. 23A349, the Agency, through Joseph Goffman, the Principal Deputy Assistant Administrator performing delegated duties of Assistant Administrator for the Office of Air and Radiation, explained in greater detail why it makes sense as both a technical and legal matter that the Federal Good Neighbor Plan can continue to be implemented in each covered state despite preliminary stays of the Plan in other states. This same reasoning applies with full force with respect to the additional states that are proposed for inclusion in these programs in this action. The declaration is included in the docket for this action.

edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at <https://www.regulations.gov> any information you consider to be CBI, Proprietary Business Information (PBI), 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. 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). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

2. Participation in Virtual Public Hearing

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/csapr/csapr-2015-ozone-naaqs> or contact Ms. Pamela Long at (919) 541-0641 and/or long.pam@epa.gov to register to speak at the virtual hearing. The last day to pre-register to speak at the hearing will be 3 working days before the hearing. On [last working day before the hearing], the EPA will post a general agenda for the hearing that will list pre-registered speakers in approximate order at: <https://www.epa.gov/csapr/csapr-2015-ozone-naaqs>.

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. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk. The EPA will make every effort to accommodate all speakers who arrive and register, although preferences on speaking times may not be able to be fulfilled. Each commenter will have 3 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically by emailing it to Ms. Pamela Long. The EPA also recommends submitting the text of your oral comments 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 comments and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing are posted online at <https://www.epa.gov/csapr/csapr-2015-ozone-naaqs>. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact Ms. Pamela Long at (919) 541-0641 and/or long.pam@epa.gov to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

The EPA will not provide audiovisual equipment for presentations unless the Agency receives special requests in advance. Commenters should notify Ms. Pamela Long when they pre-register to speak that they will need specific equipment. If you require the services of an interpreter or special accommodations such as audio description, please pre-register for the hearing with Ms. Pamela Long and describe your needs by [DATE 1 WEEK BEFORE THE PUBLIC HEARING DATE]. The EPA may not be able to arrange accommodations without advance notice.

III. Background

A. Description of Statutory Background

On October 1, 2015, the EPA promulgated a revision to the ozone NAAQS (2015 8-hour ozone NAAQS), lowering the level of both the primary and secondary standards to 0.070 parts per million (ppm) for the 8-hour standard.²⁴ Section 110(a)(1) of the CAA requires states to submit, within 3 years after promulgation of a new or revised standard, SIP submissions meeting the applicable requirements of CAA section 110(a)(2).²⁵ One of these applicable requirements is found in CAA section 110(a)(2)(D)(i)(I), otherwise known as the “good neighbor” or “interstate transport” provision, which generally requires that SIPs contain adequate

provisions to prohibit in-state emissions activities from having certain adverse air quality effects on other states due to interstate transport of pollution. There are two so-called “prongs” within CAA section 110(a)(2)(D)(i)(I). A SIP for a new or revised NAAQS must contain adequate provisions prohibiting any source or other type of emissions activity within the State from emitting air pollutants in amounts that will significantly contribute to nonattainment of the NAAQS in another State (Prong 1) or interfere with maintenance of the NAAQS in another State (Prong 2). The EPA and states must give independent significance to Prong 1 and Prong 2 when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).²⁶

On January 31, 2023, the EPA finalized disapproval of 19 SIP submissions and partially approved and partially disapproved two SIP submissions addressing the good neighbor provision for the 2015 ozone NAAQS. The EPA's evaluation for those actions applied uniform, nationwide analytical methods, policy judgments, and interpretation with respect to the same CAA obligations, *i.e.*, implementation of good neighbor requirements under CAA section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS for states across the country. To maintain consistency across all states in light of the final analytical conclusions reached in that action and the separate Federal Good Neighbor Plan, the EPA indicated it would take subsequent action on remaining SIP submissions addressing interstate transport obligations for the 2015 ozone NAAQS.²⁷ The EPA also indicated it would address previous final actions on SIP submissions for states where the EPA's final analysis suggested the State may be significantly contributing to nonattainment or interfering with maintenance. In the Federal Good Neighbor Plan, finalized on March 15, 2023, the EPA indicated it would address these and any outstanding FIP obligations in a future action for these states, which included the five states included here and Wyoming.²⁸ The EPA finalized its approval of the SIP submission from Wyoming on December 13, 2023.²⁹ This action proposes to

²⁴ National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015). Although the level of the standard is specified in the units of ppm, ozone concentrations are also described in ppb. For example, 0.070 ppm is equivalent to 70 ppb.

²⁵ SIP submissions that are intended to meet the applicable requirements of CAA section 110(a)(1) and (2) of the CAA are often referred to as infrastructure SIPs and the applicable elements under CAA section 110(a)(2) are referred to as infrastructure requirements.

²⁶ See *North Carolina v. EPA*, 531 F.3d 896, 909–11 (D.C. Cir. 2008).

²⁷ 88 FR 36656.

²⁸ 88 FR 36654 at 36656.

²⁹ See Air Plan Approval; Wyoming; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards, 88 FR 54998 (August 14, 2023). The EPA signed the

address the five additional remaining SIP submissions and FIP obligations.

B. Description of the EPA's 4-Step Interstate Transport Regulatory Process

For decades, when evaluating SIPs and formulating FIPs, EPA has consistently utilized the 4-step interstate transport framework (or 4-step framework), which was developed to give meaning to the critical statutory terms in CAA section 110(a)(2)(D)(i)(I) and to provide a reasonable organization to the analysis of the complex air quality challenge of interstate ozone transport. The EPA has addressed the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) with respect to prior NAAQS using the 4-step framework in several regulatory actions, including the CSAPR, which addressed interstate transport with respect to the 1997 ozone NAAQS as well as the 1997 and 2006 fine particulate matter standards,³⁰ the CSAPR Update³¹ and the Revised CSAPR Update, both of which addressed the 2008 ozone NAAQS.³² For the 2015 ozone NAAQS, the EPA uses this framework in evaluating SIP submissions (while considering any alternative approaches states may propose) and applied this framework in the Federal Good Neighbor Plan.³³

Shaped through the years by input from State air agencies³⁴ and other stakeholders on the EPA's prior interstate transport rulemakings and SIP submission actions,³⁵ as well as a number of court decisions, the EPA has developed and used the 4-step interstate transport framework to evaluate State's obligations to eliminate interstate

transport emissions under the interstate transport provision for the ozone NAAQS: (1) identify monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS (*i.e.*, nonattainment and/or maintenance receptors); (2) identify states that impact those air quality problems in other (*i.e.*, downwind) states sufficiently such that the states are considered to "contribute" (*i.e.*, are considered "linked") to those receptors and whose emissions therefore warrant further review and analysis; (3) identify the emissions reductions necessary (if any), applying a multifactor analysis, to eliminate each linked upwind State's significant contribution to nonattainment or interference with maintenance of the NAAQS at the locations identified in Step 1; and (4) adopt permanent and enforceable measures needed to achieve those emissions reductions. EPA does not require states to use the 4-step framework in good neighbor SIP submissions, but it is a useful organizational tool that has been upheld by the Supreme Court as "permissible, workable, and equitable." *EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 524 (2014).

The general steps of this framework allow for some methodological variation, and this can be seen in the evolution of the EPA's analytic process across its prior rulemakings. This also means states have some flexibility in developing analytic methods within this framework (and may also attempt to justify an alternative framework altogether). The four steps of the framework provide a reasonable organization to the analysis of the complex air quality challenge of interstate ozone transport. As discussed further throughout this document, the EPA has organized its evaluation of good neighbor obligations around this analytical framework (including the specific methodologies within each step as evolved over the course of the CSAPR rulemakings since 2011). Where states presented alternative approaches either to the EPA's methodological approaches within the framework, or organized their analysis in some manner that differed from it entirely, the EPA has evaluated those analyses on their merits to determine compliance with the good neighbor obligation or, in some cases, identified why even if those approaches were acceptable, the State still does not meet the good neighbor requirement and therefore does not have an approvable SIP submission as a whole.

C. The EPA's Ozone Transport Modeling

The EPA has performed nationwide air quality modeling to project ozone design values that are used in combination with measured data to identify nonattainment and maintenance receptors at Step 1. To quantify the contribution of emissions from individual upwind states on 2023 and 2026 ozone design values for the identified downwind nonattainment and maintenance receptors at Step 2, the EPA has performed nationwide, state-level ozone source apportionment modeling for 2023 and 2026. The source apportionment modeling provides contributions to ozone at receptors from precursor emissions of anthropogenic NO_x and volatile organic compounds (VOCs) in individual upwind states. In this action, the EPA is proposing to apply the air quality modeling and contribution results that were derived using the 2016v3 modeling and monitoring data that informed the EPA's Step 1 and Step 2 determinations in the Federal Good Neighbor Plan—inclusive of the approach for identifying certain addition sites as violating-monitor maintenance-only receptors based on certified monitoring data and regulatory design values for 2021 and 2022. This section provides an overview of the modeling developments that resulted in those analytical conclusions, which are used here to make good neighbor determinations for these five additional states.

The EPA released several documents containing projected ozone design values, contributions, and information relevant to air agencies for evaluation of interstate transport with respect to the 2015 ozone NAAQS. First, on January 6, 2017, the EPA published a notice of data availability (NODA) in which the Agency requested comment on preliminary interstate ozone transport data including projected ozone design values and interstate contributions for 2023 using a 2011 base year platform.³⁶ In the NODA, the EPA used the year 2023 as the analytic year for this preliminary modeling because this year aligns with the expected attainment year for Moderate ozone nonattainment areas for the 2015 8-hour ozone NAAQS.³⁷ On October 27, 2017, the EPA released a memorandum (October 2017 memorandum) containing updated modeling data for 2023, which incorporated changes made in response

final approval on December 13, 2023. 88 FR 87720 (December 19, 2023).

³⁰ See Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 FR 48208 (August 8, 2011).

³¹ Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS, 81 FR 74504 (October 26, 2016).

³² In 2019, the D.C. Circuit Court of Appeals remanded the CSAPR Update to the extent it failed to require upwind states to eliminate their significant contribution by the next applicable attainment date by which downwind states must come into compliance with the NAAQS, as established under CAA section 181(a). *Wisconsin v. EPA*, 938 F.3d 303, 313 (D.C. Cir. 2019). The Revised CSAPR Update for the 2008 Ozone NAAQS, 86 FR 23054 (April 30, 2021), responded to the remand of the CSAPR Update in *Wisconsin* and the vacatur of a separate rule, the "CSAPR Close-Out," 83 FR 65878 (December 21, 2018), in *New York v. EPA*, 781 F. App'x. 4 (D.C. Cir. 2019).

³³ See 88 FR at 9338; 88 FR at 36671.

³⁴ See 63 FR 57356, 57361 (October 27, 1998).

³⁵ In addition to CSAPR rulemakings, other regional rulemakings addressing ozone transport include the "NO_x SIP Call," 63 FR 57356 (October 27, 1998), and the "Clean Air Interstate Rule" (CAIR), 70 FR 25162 (May 12, 2005).

³⁶ See Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 8-hour Ozone National Ambient Air Quality Standard (NAAQS), 82 FR 1733 (January 6, 2017).

³⁷ 82 FR at 1735.

to comments on the NODA, and was intended to provide information to assist states' efforts to develop SIP submissions to address interstate transport obligations for the 2008 ozone NAAQS.³⁸

On March 27, 2018, the EPA issued a memorandum (March 2018 memorandum) noting that the same 2023 modeling data released in the October 2017 memorandum could also be useful for identifying potential downwind air quality problems with respect to the 2015 ozone NAAQS at Step 1 of the 4-step interstate transport framework.³⁹ The March 2018 memorandum also included the then newly available contribution modeling data for 2023 to assist states in evaluating their impact on potential downwind air quality problems for the 2015 8-hour ozone NAAQS under Step 2 of the 4-step interstate transport framework.⁴⁰ The EPA subsequently issued two more memoranda in August and October 2018, providing additional information to states developing interstate transport SIP submissions for the 2015 ozone NAAQS concerning, respectively, potential contribution thresholds that may be appropriate to apply in Step 2 of the 4-step interstate transport framework, and considerations for identifying downwind areas that may have problems maintaining the standard at Step 1 of the 4-step interstate transport framework.⁴¹

Following the release of the modeling data shared in the March 2018 memorandum, the EPA performed

updated modeling using a 2016 base year emissions modeling platform (*i.e.*, 2016 Version 1 Emissions Platform Modeling, or "2016v1"). This emissions platform was developed under the EPA/Multi-Jurisdictional Organization (MJO)/state collaborative project.⁴² This collaborative project was a multi-year joint effort by the EPA, MJOs, and states to develop a new, more recent emissions platform for use by the EPA and states in regulatory modeling as an improvement over the dated 2011-based platform that the EPA had used to project ozone design values and contribution data provided in the 2017 and 2018 memoranda. The EPA used the 2016v1 emissions to project ozone design values and contributions for 2023. On October 30, 2020, in the Notice of Proposed Rulemaking for the Revised CSAPR Update, the EPA released and accepted public comment on 2023 modeling that used the 2016v1 emissions platform.⁴³ Although the Revised CSAPR Update addressed transport for the 2008 ozone NAAQS, the projected design values and contributions from the 2016v1 platform were also useful for identifying downwind ozone problems and linkages with respect to the 2015 ozone NAAQS.⁴⁴

Following the final Revised CSAPR Update, the EPA made further updates to the 2016-based emissions platform to include updated onroad mobile emissions from Version 3 of the EPA's Motor Vehicle Emission Simulator (MOVES) model (MOVES3)⁴⁵ and updated emissions projections for EGUs that reflected the emissions reductions from the Revised CSAPR Update, recent information on plant closures, and other inventory improvements. The EPA published these emissions inventories on its website in September of 2021 and invited initial feedback from states and other interested stakeholders.⁴⁶ The construct of the updated emissions platform, (*i.e.*, 2016 Version 2 Emissions Platform Modeling, or "2016v2"), is

described in the "Technical Support Document (TSD): Preparation of Emissions Inventories for the 2016v2 North American Emissions Modeling Platform," hereafter known as the 2016v2 Emissions Modeling TSD, and is included in Docket No. EPA-HQ-OAR-2021-0663. The EPA performed air quality modeling using the 2016v2 emissions to provide projections of ozone design values and contributions in 2023 and 2026 that reflect the effects on air quality of the 2016v2 emissions platform. The EPA used the results of the 2016v2 modeling to inform proposed and final actions on 2015 ozone NAAQS good neighbor obligations for Iowa and Kansas.⁴⁷

The EPA also used the 2016v2 emissions inventories and modeling to support proposed actions for several states, including the EPA's previous proposals on Arizona and Tennessee, as well as the proposed Federal Good Neighbor Plan. In response to comments received for these rulemakings, the EPA updated the 2016v2 inventories and model design to construct another emissions platform (*i.e.*, 2016 Version 3 Emissions Platform Modeling, or "2016v3"), which was used to update the air quality modeling. The EPA used this updated modeling to inform a final rulemaking taking final action on 21 interstate transport SIP submissions for the 2015 ozone NAAQS and to inform the final Federal Good Neighbor Plan.^{48 49} In its final actions on both SIP disapprovals, and the Federal Good Neighbor Plan, the EPA provided an explanation of the adjustments and other modifications made to construct the 2016v3 platform. Details on the 2016v3 air quality modeling and the methods for projecting design values and determining contributions in 2023 and 2026 based on this platform are described in the TSD titled "Air Quality

³⁸ See Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone National Ambient Air Quality Standards under Clean Air Act section 110(a)(2)(D)(i)(I), October 27, 2017, available in docket ID No. EPA-HQ-OAR-2021-0663.

³⁹ See Information on the Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards under Clean Air Act section 110(a)(2)(D)(i)(I), March 27, 2018 ("March 2018 memorandum"), available in docket ID No. EPA-HQ-OAR-2021-0663.

⁴⁰ The March 2018 memorandum, however, provided, "While the information in this memorandum and the associated air quality analysis data could be used to inform the development of these SIPs, the information is not a final determination regarding states' obligations under the good neighbor provision. Any such determination would be made through notice-and-comment rulemaking."

⁴¹ See Analysis of Contribution Thresholds for Use in Clean Air Act section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, August 31, 2018 ("August 2018 memorandum"), and Considerations for Identifying Maintenance Receptors for Use in Clean Air Act section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, October 19, 2018, available in docket ID No. EPA-HQ-OAR-2021-0663.

⁴² The results of this modeling, as well as the underlying modeling files, are included in docket ID No. EPA-HQ-OAR-2021-0663. The 2016v1 emissions modeling technical support document is available in Docket ID No. EPA-HQ-OAR-2020-0272-0187. Both dockets are available at <https://www.regulations.gov>.

⁴³ See 85 FR 68964, 68981.

⁴⁴ See the Air Quality Modeling Technical Support Document for the Final Revised Cross-State Air Pollution Rule Update, included in the Headquarters docket ID No. EPA-HQ-OAR-2021-0663.

⁴⁵ Additional details and documentation related to the MOVES3 model can be found at <https://www.epa.gov/moves/latest-version-motor-vehicle-emission-simulator-moves>.

⁴⁶ <https://www.epa.gov/air-emissions-modeling/2016v2-platform>.

⁴⁷ The EPA was obligated by consent-decree deadline to finalize its action for Iowa and Kansas by April 30, 2022, and was unable to consider or incorporate the later comments received on the 2016v2 modeling that were used to inform the 2016v3 modeling informing the final Disapproval action and final Federal Good Neighbor Plan in early 2023.

⁴⁸ "Air Plan Disapprovals; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards," 88 FR 9336 (February 13, 2023), and "Federal "Good Neighbor Plan" for the 2015 Ozone National Ambient Air Quality Standards," 88 FR 36654 (June 5, 2023).

⁴⁹ In the Federal Good Neighbor Plan, the EPA identified and finalized FIPs for 23 states. This included the 21 states included in the SIP Disapproval action, as well as Pennsylvania and Virginia. The EPA had an obligation to finalize a FIP for these two states (and Utah) following the EPA's finding of a failure to submit a SIP from these two states (84 FR 66612). The EPA has not since received SIP submissions from Pennsylvania or Virginia.

Modeling Final Rule TSD—2015 Ozone NAAQS Good Neighbor Plan,” hereafter known as the Final Good Neighbor Plan AQM TSD.⁵⁰ Additional details related to the 2016v3 emissions platform are located in the TSD titled “Preparation of Emissions Inventories for the 2016v3 North American Emissions Modeling Platform,” hereafter known as the 2016v3 Emissions Modeling TSD, included in Docket ID No. EPA–HQ–OAR–2021–0668.⁵¹

In this proposed action, the EPA primarily relies on modeling based on the 2016v3 emissions platform coupled with measured data in Steps 1 and 2 of the 4-step interstate transport framework, which will generally be referenced within this action as the “2016v3 modeling” for 2023 and 2026. As discussed further in section III.D.2. of this document, the EPA is also applying its findings regarding violating-monitor maintenance-only receptors in 2023 using certified monitoring data and regulatory design values for 2021 and 2022. The EPA used the 2016v3 modeling to calculate contributions to these receptors. By again using this same set of monitoring data and updated modeling results, the EPA is using the most current and technically appropriate information for this proposed rulemaking and also ensuring that its regulatory determinations for these remaining states are wholly consistent with the findings informing the EPA’s final determinations for all of the states included in the final Federal Good Neighbor Plan. In this proposed action, the EPA is accepting public comment on the 2016v3 modeling and the violating-monitor methodology, solely as they relate to Arizona, Iowa, Kansas, New Mexico, and Tennessee interstate transport obligations for the 2015 ozone NAAQS. The EPA is not reopening the modeling in relation to any other State or regulatory action. Any comments received on the modeling that are not relevant to the evaluation of these states’ interstate transport obligations will be treated as beyond the scope of this action.

States may have chosen to rely on the results of prior versions of EPA’s modeling and/or alternative modeling performed by states or MJOs to evaluate downwind air quality problems and contributions as part of their SIP submissions. The EPA is not proposing to disapprove any State’s submission in

this action based on the State’s choice of modeling, but, consistent with its disapproval action, based on the EPA’s evaluation of the entire record, which aims to factually determine whether states are projected to significantly contribute to or interfere with maintenance in the 2023 analytical year. See 88 FR at 9343. In section IV.B. of this document, the EPA evaluates how Arizona, Iowa, Kansas, New Mexico, and Tennessee used air quality modeling information in their SIP submissions.

A summary of the methodology and results of the 2016v3 modeling for 2023 and 2026, along with the application of the EPA’s Step 1 and Step 2 methodology for identifying receptors and upwind states that contribute to those receptors can be found in the Final Good Neighbor Plan AQM TSD. That document also contains explanations as to how current measured ozone levels based on data for 2021 and 2022 at other monitoring sites (*i.e.*, monitoring sites that are not projected to be receptors in 2023 based on air quality modeling) confirm the likely continuation of elevated ozone levels in 2023 at these locations. This analysis shows that each of the five states in this action are linked at or above (*i.e.*, contributing equal to or more than) 1 percent of the NAAQS to one or more of these monitors. Kansas and Tennessee are linked only to violating-monitor receptors, and not to modeling-based receptors. In recognition that the EPA had not proposed these sites as receptors, linkages to such receptors were used only in a “confirmatory” way to inform the final Disapproval action and Good Neighbor Plan (*i.e.*, to reinforce linkage findings as to states that were otherwise linked to modeling-based receptors). In this proposed action, the EPA finds the existence of such linkages is sufficient to establish that a State contributes to such receptors and is thus an adequate basis on which to propose disapproval of the SIP submissions from Kansas and Tennessee.

D. The EPA’s Approach To Evaluating Interstate Transport for the 2015 Ozone NAAQS

The EPA has applied a consistent set of policy judgments across all states for purposes of evaluating interstate transport obligations and the approvability of interstate transport SIP submissions for the 2015 ozone NAAQS under CAA section 110(a)(2)(D)(i)(I) and proposes to continue to do so in this action. These policy judgments conform with relevant case law and past Agency practice as reflected in the CSAPR and related rulemakings. Employing a

nationally consistent approach is particularly important in the context of interstate ozone transport, which is a regional-scale pollution problem characterized by the collective contribution from many upwind states to geographically dispersed monitors over distances of hundreds of miles. Effective policy solutions to the problem of interstate ozone transport going back to the NO_x SIP Call have necessitated the application of a uniform framework of policy judgments to ensure an “efficient and equitable” approach. See *EME Homer City Generation, LP v. EPA*, 572 U.S. 489, 519 (2014).

In the March, August, and October 2018 memoranda, the EPA recognized that states may be able to establish alternative approaches to addressing their interstate transport obligations for the 2015 ozone NAAQS that vary from a nationally uniform framework. The EPA emphasized in these memoranda, however, that such alternative approaches must be technically justified and appropriate in light of the facts and circumstances of each particular State’s SIP submission. In general, the EPA continues to believe that deviation from a nationally consistent approach to ozone transport must have a well-documented technical basis that is consistent with CAA obligations and relevant case law. Where states submitted SIP submissions that rely on any such potential concepts as the EPA or others may have identified or suggested in the past, the EPA will evaluate whether the State adequately justified the technical and legal basis for doing so.

The EPA notes that certain potential concepts included in an attachment to the March 2018 memorandum require unique consideration, and these ideas do not constitute Agency guidance with respect to interstate transport obligations for the 2015 ozone NAAQS. Attachment A to the March 2018 memorandum identified a “Preliminary List of Potential Flexibilities” that could potentially inform SIP development. However, the EPA made clear in both the March 2018 memorandum⁵² and in Attachment A that the list of ideas was not endorsed by the Agency but rather “comments provided in various forums” on which the EPA sought “feedback from interested stakeholders.”⁵³ Further, Attachment A stated, “EPA is not at this time making any determination that the ideas discussed below are consistent with the requirements of the CAA, nor are we specifically recommending that states

⁵⁰ Air Quality Modeling Final Rule Technical Support Document—2015 Ozone NAAQS Good Neighbor Plan in Docket ID No. EPA–HQ–OAR–2021–0668.

⁵¹ 2016v3 Emissions Modeling TSD in Docket ID No. EPA–HQ–OAR–2021–0668.

⁵² March 2018 memorandum, Attachment A.

⁵³ *Id.* at A–1.

use these approaches.”⁵⁴ Attachment A to the March 2018 memorandum, therefore, does not constitute Agency guidance, but was intended to generate further discussion around potential approaches to addressing ozone transport among interested stakeholders. To the extent states sought to develop or rely on one or more of these ideas in support of their SIP submissions, the EPA will thoroughly review the technical and legal justifications for doing so.

The remainder of this section describes the EPA’s analytic framework and interpretation of the critical terms of the good neighbor provision with respect to analytic year, definition of nonattainment and maintenance receptors, selection of contribution threshold, and multifactor control strategy assessment.

1. Selection of Analytic Years

In this section, the EPA describes its process for selecting analytic years for air quality modeling and analyses performed to identify nonattainment and maintenance receptors and identify upwind State linkages. The EPA is retaining the 2023 and 2026 analytical years used to inform the obligations of the 23 states included in the Federal Good Neighbor Plan, to ensure consistency and equitable treatment of all states. In the Federal Good Neighbor Plan, the EPA evaluated air quality to identify receptors at Step 1 and evaluate interstate contributions at Step 2 for two analytic years: 2023 and 2026.⁵⁵ These years are the last full ozone seasons before the Moderate and Serious area attainment dates for the 2015 ozone NAAQS (ozone seasons for purposes of the Federal Good Neighbor Plan run each year from May 1–September 30, *see* 40 CFR 52.38(b)(1) and 40 CFR 52.40(c)(1)). To demonstrate attainment by these deadlines, downwind states would be required to rely on design values calculated using ozone data from 2021 through 2023 and 2024 through 2026, respectively. Areas that do not attain by the deadline may be “bumped up” to a higher nonattainment classification level per CAA sections 181 and 182, thereby incurring additional ongoing obligations. Thus, in the Federal Good Neighbor Plan, consistent with each of its prior good neighbor rulemakings, the EPA focused

its analysis on the last full ozone seasons before the attainment dates (*i.e.*, 2023 and 2026).

The Agency recognizes that in applying its 2023 and 2026 analytics to inform this action, it may be perceived as acting inconsistently with a longstanding policy of always considering a future analytic year from the standpoint of the timing of its rulemaking action. However, the EPA determined that several important, overriding considerations warrant adopting this approach in this supplemental rulemaking. As explained in section I.A. of this document, it is imperative to maintain a consistent set of analytical and policy determinations across all states in the context of addressing the interstate ozone problem; the EPA is doing so by using a consistent set of data and analytical conclusions between the states included in this action and those for which the EPA has already rendered final determinations in the final SIP Disapproval action and the Federal Good Neighbor Plan. Were the EPA to conduct a new set of air quality analyses tied to years beyond 2023 or 2026, the EPA would separately evaluate these states using different data than that which informed and defined the obligations of all other states, solely as a result of the timing of the EPA’s action on these states. Where the need for parity among states or other jurisdictions in like circumstances warrants it, courts have recognized that it may be appropriate for agencies like the EPA to rely on a unified dataset to ensure consistency in treatment. *See Bd. County Commissioners of Weld County v. EPA*, 72 F.4th 284, 290 (D.C. Cir. 2023) (upholding as reasonable the EPA’s determination that “greater parity among counties and faster turnaround [] make the original data a better choice than partial updating”). The importance of use of a single, already-developed dataset focused on the years 2023 and 2026 to define good neighbor obligations for all states to ensure consistency among states and for “faster turnaround” to complete this supplemental rulemaking is, in the EPA’s judgment, sufficiently compelling to justify this approach here.

The EPA’s use of a common and unified dataset here is consistent with all of its past good neighbor rulemakings, including those in which the EPA conducted updated air quality analysis to address remaining good neighbor obligations. In both the CSAPR Update and the Revised CSAPR Update, the EPA took action to address good neighbor FIP actions that had been remanded to the EPA. In each case, the

EPA addressed the remanded obligations for all of the covered states through analysis of a new analytic year. This ensured consistency among all of the states where there were good neighbor obligations that needed to be addressed. *See, e.g.*, 86 FR 23067–68 (discussing error correction for Kentucky “consistent with EPA’s methodology to address the other 20 states” included in that action). Further, the EPA already had updated modeling at hand that could inform its new action. *See, e.g., id.* at 23074, 23079–80. Likewise, where all of a group of states’ obligations were being addressed on remand from an action that had not been vacated (as was the case in both the CSAPR Update and the Revised CSAPR Update), it was important to reflect the emissions reductions and air quality improvements that were already being achieved from the non-vacated action in the baseline. *See, e.g., id.* at 23075. In this case, the EPA is not re-evaluating a group of states but addressing additional states in a manner that ensures consistent treatment with the first set of states. This circumstance is analogous to the supplemental rulemaking the EPA undertook soon following the original CSAPR rulemaking to add several states to those programs based on the same data and analysis that informed the CSAPR. *See* 76 FR 80760 (December 27, 2011). In the EPA’s judgment, the relevant considerations therefore weigh in favor of using the currently available air quality data that has already been used to define other states’ obligations.

In addition, like the CSAPR supplemental rulemaking, the timing of this action is the result of procedural happenstance, rather than a substantive difference in the circumstances of any of these five states. This timing was driven by the nature of the EPA’s prior proposed or final actions, or lack of such actions, that had been taken at the time the EPA completed its final, updated air quality analysis informing its final determinations on other states’ obligations in the Federal Good Neighbor Plan (explained further in section III.C. of this document). This final analysis of obligations based on 2023 and 2026 analytics necessitated the EPA’s reevaluation of its proposals on Arizona and Tennessee’s SIP submissions, as well as the EPA’s past final actions on Iowa and Kansas’ SIPs.⁵⁶ In these circumstances, given the potential change in the status of these states, the EPA also found it would be appropriate to provide an opportunity

⁵⁴ *Id.*

⁵⁵ While the 2023 analytic year provides a sufficient basis to act on the SIP submissions in this action, consistent with the EPA’s Disapproval action, *see* 88 FR 9340–41, the EPA uses the 2026 analytic year to ensure a complete Step 3 analysis in the context of developing the FIP, *see* 88 FR 36694.

⁵⁶ The EPA has not taken any previous proposed or final action on New Mexico’s SIP submission.

for public comment on the EPA's changed basis for action.

Further, shifting the analysis of good neighbor obligations forward to a new analytic year for these five states would not be relevant to a proper definition of these good neighbor obligations, and switching the analytic year(s) for just these five states could create an inequitable result both amongst other upwind states and between these five states and the downwind states to which they are linked. Creating a different set of data for a later year for these states, when the Federal Good Neighbor Plan has already defined requirements and is in effect for certain other states, would introduce an interdependency, or "who goes first," problem that the EPA's framework generally is designed to avoid. *See Ky. Energy & Env't Cabinet v. EPA*, No. 23–3605 (6th Cir. Nov. 9, 2023), Slip Op. at 8. The EPA is not reopening the determinations made for the 23 upwind states covered in the Federal Good Neighbor Plan, and 2023 and 2026 were appropriately selected as the analytical years to inform the EPA's evaluation of these states. *See* 88 FR at 36694–96. These years are associated with the statutory attainment schedule faced by the downwind states with designated nonattainment areas where the identified receptors are located. It is at the least reasonable, therefore, to align these five states' evaluation with the remainder of the states in the country, which will maintain parity among all jurisdictions, which is preferable to only "partially updating" the analysis in the case of a handful of states. *Weld County*, 72 F.4th at 290. This is a particularly important consideration in implementing the good neighbor provision for ozone. The EPA must ensure each state is held to the elimination of its own significant contribution. *See North Carolina v. EPA*, 531 F.3d 896, 920–21 (D.C. Cir. 2008). And interstate ozone pollution presents a "collective contribution" problem in which the EPA must allocate a fair share of responsibility among sources across multiple states. *See Maryland v. EPA*, 1185 F.3d at 120304 (D.C. Cir. 2020); *id.* at 1204 ("So long as upwind sources significantly contribute to [a state's] nonattainment at its 2021 [Marginal] attainment deadline, they violate the Good Neighbor Provision.").

As the *Maryland* court recognized, the consequences on downwind nonattainment areas from failure to obtain relief from upwind significant contribution are not just continuing poor air quality, but also regulatory requirements that apply for years into the future, including "a requirement to

provide for annual emissions reductions in SIPs." *Id.* (citing CAA section 182(b)). The relief that can be afforded through addressing the upwind states' significant contribution, as proposed in this action, will therefore potentially lessen regulatory burdens on downwind states that Congress commanded they are not to bear alone. *See* 88 FR 36840 (discussing the history of downwind states' and the EPA's reliance on emissions reductions achieved through prior good neighbor rules in, for example, redesignation actions and maintenance plans); *cf. Maryland*, 958 F.3d at 1200 (a state that cannot obtain relief from an upwind state's significant contribution to a continuing nonattainment designation "is stuck in regulatory limbo"). Thus, using a common dataset makes good sense in this context; it is consistent with the requirements and the purpose of the good neighbor provision, and it ensures these obligations are implemented both expeditiously and in a consistent and equitable manner. *Weld County*, 72 F.4th at 290.⁵⁷

The use of a common set of air quality data was upheld in *Weld County*. The court, however, went on to find that another portion of the EPA's action under review constituted impermissible retroactive rulemaking, because it "effectively backdated" a nonattainment designation, leaving a state that would have had a three-year period to reach attainment in the position of "missing a compliance deadline that passed before the underlying legal obligation was imposed." 72 F.4th at 293. This proposed action does not operate retroactively. The EPA's use of the 2023 analytic year does not in and of itself impose any obligations on any sources or states. Rather it provides a common dataset to assess whether any state is contributing to downwind problems attaining the NAAQS. The EPA proposes to set compliance obligations based on the amount of time needed for sources to come into compliance and does not propose to impose liability on such sources for not meeting the proposed obligations at some point in the past. *See* section VII.A.4. and B. of

⁵⁷ While use of a common dataset makes sense for the reasons stated, the EPA notes that it is not aware of other data sets, including either monitoring data or modeling projections, that would suggest alternative regulatory conclusions from those proposed here. As evidenced by the most recent certified monitoring data and design values from 2021 and 2022 used in the violating-monitor receptor-identification methodology, relatively elevated ozone levels exceeding the NAAQS continue to be observed throughout much of the continental U.S., including in the designated nonattainment areas where many of the ozone-transport receptors identified in the Federal Good Neighbor Plan are located.

this document. Nor would the proposed rule apply retroactively to the five states with SIP submissions proposed to be disapproved. The EPA is not proposing to backdate the date of finalization of these proposed disapprovals to sometime in the past. Rather, if the proposed disapprovals are finalized, the only legal consequence—the establishment of a duty on the EPA to promulgate a FIP—would run from the date a final action is taken. Unlike the three-year "runway" allowed to reach attainment that the court found had been impermissibly denied to the state in *Weld County*, 72 F.4th at 293, the statute affords no such period following a SIP disapproval. CAA section 110(c)(1). The EPA need not wait a single day to promulgate a FIP upon issuing a disapproval of a SIP submission. *EME Homer City*, 489 U.S. at 509. Nor is the EPA obligated to give states a second chance to submit a SIP before issuing a FIP. *Id.* Nonetheless, the states covered in this supplemental proposed rulemaking have been on notice since the issuance of the 2016v3 modeling and violating-monitor methodology in connection with the SIP Disapproval and Federal Good Neighbor Plan actions in winter of 2023 that they may be subject to a good neighbor FIP due to identified linkages with downwind receptors. 88 FR 36656. None of these five states has moved since that time to submit a revised SIP submission to address the relevant requirements.

For consistency, the Agency similarly conducted its overcontrol analysis for this action using the 2023 and 2026 data (*see* section VI.D. of this document). The EPA recognizes that it is appropriate to provide sufficient lead time to allow sources in these five states to comply with the proposed requirements. Based on the compliance-timing analysis conducted in the final Federal Good Neighbor Plan and applied here (as discussed in section VII. of this document), the dates proposed for the onset of these requirements for these five states fall after the 2023 and 2026 analytic years. This too is a matter of happenstance and does not justify a deviation from the definition of these states' good neighbor obligations. Similarly, assuming favorable outcomes in the ongoing litigation resulting in stays of the Federal Good Neighbor Plan for several states pending judicial review, the EPA anticipates adjusting the timing of compliance obligations if these states are eventually made subject to the Federal Good Neighbor Plan. These circumstances are analogous to an issue the EPA addressed in the final

Federal Good Neighbor Plan regarding the ability of individual sources to apply for and obtain compliance extensions. The EPA explained that where sources obtained such extensions, the EPA did not intend to conduct further analysis of whether those reductions were still required based on updated air quality analysis. As the EPA explained, the Agency did not think individual sources should gain the benefit of delaying emissions reductions simply in the hopes that they could show those reductions would be overcontrol. This would introduce an inter-dependency into the analysis, whereas each source must be held to the elimination of its portion of significant contribution. Necessity, the EPA explained, may demand some additional amount of time for compliance, but equity demands that individual sources not gain an untoward advantage from delay and reliance on other sources' timelier compliance. *See* 88 FR at 36750 n.253. Thus, here, the EPA continues to conduct its overcontrol analysis using the common datasets for 2023 and 2026, to ensure consistent and equitable determinations for what constitutes "significant contribution" even if the implementation of those emissions reductions may be delayed in certain states or for certain sources.

Thus, the EPA proposes to continue to use its 2023 and 2026 analytics, to ensure parity by holding all states to a consistent set of data in defining good neighbor obligations for the 2015 ozone NAAQS, to avoid improperly shifting the burden of emissions reductions to other upwind and downwind states, and to provide for an efficient and administratively workable resolution of these remaining obligations for five additional states.

2. Step 1 of the 4-Step Interstate Transport Framework

In Step 1, the EPA identifies monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS in the 2023 analytic year. This approach reflects the EPA's interpretation of the terms "nonattainment" and "maintenance" as used in the good neighbor provision in the context of the ozone NAAQS. *See* 88 FR at 9341–42. Where the EPA's analysis shows that a site does not meet the definition of a nonattainment or maintenance receptor, the EPA excludes that site from further analysis under the EPA's 4-step interstate transport framework. At Step 2 of the 4-step interstate transport framework, the EPA considers those sites identified as a nonattainment or maintenance receptor

in 2023 and identifies which upwind states contribute to those receptors above the contribution threshold.

The EPA's approach to identifying ozone nonattainment and maintenance receptors in this action is the same as that used in the Federal Good Neighbor Plan.⁵⁸ This approach gives independent consideration to both the "contribute significantly to nonattainment" and the "interfere with maintenance" prongs of CAA section 110(a)(2)(D)(i)(I), consistent with the D.C. Circuit's direction in *North Carolina*.⁵⁹ To summarize this methodology:

The EPA identifies nonattainment receptors as those monitoring sites that are projected to have average design values that exceed the NAAQS and that are also measuring nonattainment based on the most recent monitored design values. This approach is consistent with prior transport rulemakings, such as the CSAPR Update, where the EPA defined nonattainment receptors as those monitoring sites that both measure nonattainment based on recent monitoring data (here, using certified 2021 data to be consistent with the analysis in the Good Neighbor Plan) and that the EPA modeling projected to be in nonattainment in the analytic year (*i.e.*, 2023).^{60 61}

In addition, the EPA identified a receptor to be a "maintenance" receptor for purposes of defining interference with maintenance, consistent with the method used in the CSAPR and upheld by the D.C. Circuit in *EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118, 136 (D.C. Cir. 2015) (*EME Homer City II*).⁶² Specifically, the EPA identified maintenance receptors as those receptors that would have difficulty

maintaining the relevant NAAQS in a scenario that takes into account historical variability in air quality at that receptor. The variability in air quality was determined by evaluating the "maximum" future design value at each receptor based on a projection of the maximum measured design value over the relevant period. The EPA interprets the projected maximum future design value to be a potential future air quality outcome consistent with the meteorology that yielded maximum measured concentrations in the ambient data set analyzed for that receptor (*i.e.*, ozone conducive meteorology). The EPA also recognizes that previously experienced meteorological conditions (*e.g.*, dominant wind direction, temperatures, and air mass patterns) promoting ozone formation that led to maximum concentrations in the measured data may reoccur in the future. The maximum design value gives a reasonable projection of future air quality at the receptor under a scenario in which such conditions do, in fact, reoccur. The projected maximum design value is used to identify upwind emissions that, under those circumstances, could interfere with the downwind area's ability to maintain the NAAQS.

Nonattainment receptors are also, by definition, maintenance receptors, and so the EPA often uses the term "maintenance-only" to refer to those receptors that are not nonattainment receptors. Consistent with the concepts for maintenance receptors, as described earlier, the EPA identifies "maintenance-only" receptors as those monitoring sites that have projected average design values above the level of the applicable NAAQS, but that are not currently measuring nonattainment based on the most recent official design values.⁶³ In addition, those monitoring sites with projected average design values below the NAAQS, but with projected maximum design values above the NAAQS are also identified as "maintenance-only" receptors, even if they are currently measuring nonattainment based on the most recent official design values.

The Agency has looked closely at measured ozone levels at ambient monitoring sites in 2021 and 2022 for the purposes of informing the identification of potential additional receptors in 2023. As explained in more detail in the February 13, 2022, final

⁵⁸ *See* Air Quality Modeling Final Rule Technical Support Document—2015 Ozone NAAQS Good Neighbor Plan in Docket ID No. EPA-HQ-OAR-2021-0668 for additional details on the EPA's evaluation nonattainment and maintenance receptor identification.

⁵⁹ *See North Carolina v. EPA*, 531 F.3d at 910–11 (holding that the EPA must give "independent significance" to each prong of CAA section 110(a)(2)(D)(i)(I)).

⁶⁰ The 2021 design values were the most current official design values available for use in the 2016v3 modeling. The 2021 ozone design values, by monitoring site, can be found in the file "Final GNP O3 DVs Contributions", in Docket ID No. EPA-HQ-OAR-2021-0668.

⁶¹ *See* 81 FR 74504 (October 26, 2016). This same concept, relying on both current monitoring data and modeling to define nonattainment receptor, was also applied in CAIR. *See* 70 FR at 25241, 25249 (January 14, 2005); *see also North Carolina*, 531 F.3d at 913–14 (affirming as reasonable the EPA's approach to defining nonattainment in CAIR).

⁶² *See* 76 FR 48208 (August 8, 2011). CSAPR Update and Revised CSAPR Update also used this approach. *See* 81 FR 74504 (October 26, 2016) and 86 FR 23054 (April 30, 2021).

⁶³ The Agency often uses the terms maintenance receptor and maintenance-only receptor interchangeably when discussing maintenance receptors that are not also nonattainment receptors.

action disapproving 19 states' good neighbor SIP submissions, and partially approving and partially disapproving 2 states' good neighbor SIP submissions ("Disapproval action"), *see* 88 FR at 9349–50, the EPA finds there is a basis to consider certain sites with elevated ozone levels that are not otherwise identified as receptors to be an additional type of maintenance-only receptor given the likelihood that ozone levels above the NAAQS could persist at those locations through at least 2023. These are referred to as violating-monitor maintenance-only receptors (violating-monitor receptors). In this action, the EPA proposes to use certified ambient monitoring data as an additional method to identify maintenance-only receptors. More specifically, violating-monitor receptors are monitoring sites with measured 2021 and 2022 design values and 2021 and 2022 4th high maximum daily average 8-hour ozone concentrations that exceed the NAAQS, despite having model-projected average and maximum design values for 2023 below the NAAQS.⁶⁴ The EPA finds these sites are at continuing risk of failing to maintain the 2015 ozone NAAQS, which justifies categorizing these sites as maintenance-only receptors. By applying the criteria that certified 2021 and 2022 design values and 2021 and 2022 4th high maximum daily average 8-hour ozone concentrations must all exceed the NAAQS the EPA gives due consideration to both measured air quality data and its modeling projections. This reasonably identifies monitoring sites as receptors in 2023 using this methodology. If sites do not meet these criteria, then the EPA could reasonably anticipate these sites to not have a problem maintaining the NAAQS in 2023 and should therefore not be considered receptors.⁶⁵

The EPA is not reopening its Step 1 methodologies or determinations in this action as to the 23 states included in the Federal Good Neighbor Plan. The EPA proposes to apply this same methodology to Arizona, Iowa, Kansas, New Mexico, and Tennessee. Comments

that are unrelated to or go beyond the application of these methodologies to these five states will be treated as beyond the scope of this action.

3. Step 2 of the 4-Step Interstate Transport Framework

In Step 2 the contribution of each upwind State to each receptor in the 2023 analytic year is quantified. This approach reflects how the Agency gives meaning to the term "contribute" in the good neighbor provision in relation to the "collective contribution" problem posed by interstate ozone pollution. *See* 88 FR at 9342. The contribution metric used in Step 2 is defined as the average impact from each State to each receptor on the days with the highest ozone concentrations at the receptor based on the 2023 modeling. If a State's contribution value does not equal or exceed the threshold of 1 percent of the NAAQS (*i.e.*, 0.70 ppb for the 2015 ozone NAAQS), the upwind State is not "linked" to a downwind air quality problem, and the EPA, therefore, concludes that the State does not contribute significantly to nonattainment or interfere with maintenance of the NAAQS in the downwind states. However, if a State's average contribution equals or exceeds the 1 percent threshold, the EPA further evaluates the State's emissions in Step 3, considering both air quality and cost as part of a multi-factor analysis, to determine what, if any, emissions might be deemed "significant" and, thus, must be eliminated pursuant to the requirements of CAA section 110(a)(2)(D)(i)(I).

In this proposed action, the EPA relies in the first instance on the 1 percent threshold for the purpose of evaluating a State's contribution to nonattainment or maintenance of the 2015 ozone NAAQS (*i.e.*, 0.70 ppb) at downwind receptors. This is consistent with the Step 2 approach that the EPA applied in the Disapproval action and in the Federal Good Neighbor Plan. The EPA has acknowledged that states may have been able to justify use of a different threshold at Step 2. For reasons explained in section IV. of this document, no State included in this action successfully made this demonstration. In addition, the EPA explained in both the Disapproval action and in the Federal Good Neighbor Plan that the need for consistent treatment of all states counsels against recognizing alternative thresholds on a state-by-state basis. Based on its experience since the release of the August 2018 memorandum, the EPA has also determined, as explained in the Disapproval action and Federal

Good Neighbor Plan, that it is not a good use of Agency resources nor is it wise policy for the EPA to attempt to justify the use of an alternative threshold on behalf of any State that failed to conduct an adequate analysis itself. Likewise, maintaining continuity across ozone NAAQS through consistent application of a 1 percent of NAAQS threshold at Step 2 is appropriate, so that, as the NAAQS is revised and made more protective, the contribution threshold is correspondingly adjusted as well. *See* 88 FR at 36712–17; 88 FR at 9371–75. *See also* 86 FR at 23085 (use of 1 percent threshold in the Revised CSAPR Update); 81 FR at 74518 (basis for use of 1 percent threshold for the 2008 ozone NAAQS in the CSAPR Update); 76 FR at 48237–38 (original determination to use 1 percent threshold for the 1997 ozone NAAQS in CSAPR).

Therefore, application of a consistent contribution threshold is important to identify those upwind states that should have responsibility for addressing their contribution to the downwind nonattainment and maintenance problems to which they collectively contribute. Continuing to use 1 percent of the NAAQS as the screening metric to evaluate collective contribution from many upwind states also allows the EPA (and states) to apply a consistent framework to evaluate interstate emissions transport under the interstate transport provision from one NAAQS to the next and helps ensure that good neighbor obligations align with the stringency of the NAAQS.

The issue of the appropriate contribution threshold to apply was thoroughly addressed in the Disapproval action and the Federal Good Neighbor Plan rulemakings, and the EPA responded to numerous comments on this topic. The EPA is not reopening this issue in this action, except as to the question of whether there is any reason to regard the Step 2 contribution threshold differently for any of these five additional states. The Agency, however, sees no basis to do so.

4. Step 3 of the 4-Step Interstate Transport Framework

At Step 3 of the 4-step interstate transport framework, the EPA further evaluates a State's emissions, in light of multiple factors, including air quality and cost considerations, to determine what, if any, emissions significantly contribute to nonattainment or interfere with maintenance and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I). This approach reflects the EPA's interpretation of the phrases "contribute significantly" or "interfere

⁶⁴ A design value is calculated using the annual fourth-highest maximum daily 8-hour ozone concentration averaged over 3 years.

⁶⁵ We also note that 2023 monitoring data is not yet certified, and further, because the Federal Good Neighbor Plan was in effect in several states during the 2023 ozone season (and sources may have otherwise voluntarily taken emissions-reduction measures consistent with the Federal Good Neighbor Plan either earlier than the effective date or in states where the Federal Good Neighbor Plan was stayed), the 2023 monitoring data is less reliable for use in establishing an air quality baseline, *i.e.*, one in the absence of the Federal Good Neighbor Plan.

with maintenance” as used in the good neighbor provision in the context of the ozone NAAQS. *See* 88 FR at 9342–43.

Under the EPA’s longstanding approach to eliminating significant contribution to nonattainment and interference with maintenance, at Step 3, a multi-factor assessment of potential emissions controls would be conducted for states linked at Step 1 and 2. The EPA’s analysis at Step 3 in prior Federal actions addressing interstate transport requirements has primarily focused on an evaluation of cost-effectiveness of potential emissions controls (on a marginal cost-per-ton basis), the total emissions reductions that may be achieved by requiring such controls (if applied across all linked upwind states), and an evaluation of the air quality impacts such emissions reductions would have on the downwind receptors to which a State is linked; other factors may potentially be relevant if adequately supported.

The EPA has consistently applied this general approach to Step 3 when identifying emissions contributions that the Agency has determined to be “significant” (or interfere with maintenance) in each of its prior Federal and regional ozone transport rulemakings, and this interpretation of the statute has been upheld by the Supreme Court. *See EME Homer City*, 572 U.S. 489, 519 (2014). While the EPA has not directed states that they must conduct a Step 3 analysis in precisely the manner the EPA has done in its prior regional transport rulemakings, State implementation plans addressing the obligations in CAA section 110(a)(2)(D)(i)(I) must prohibit “any source or other type of emissions activity within the State” from emitting air pollutants which will contribute significantly to downwind air quality problems. Thus, states must undertake an analysis similar to the EPA’s analysis (or an alternative approach to defining “significance” that comports with the statute’s objectives) to determine whether and to what degree emissions from a State should be “prohibited” to eliminate emissions that will “contribute significantly to nonattainment in or interfere with maintenance of” the NAAQS in any other state. *See* 88 FR at 9342–43, 9375–76.

In general, where the EPA’s or state-provided alternative air quality and contribution modeling establishes that a State is linked at Steps 1 and 2, it will be insufficient at Step 3 for a State merely to point to its existing rules requiring control measures as a basis for SIP submission approval. In general, the emissions-reducing effects of all existing

emissions control requirements are already reflected in the future year projected air quality results of the modeling for Steps 1 and 2.

If the State is shown to still be linked to one or more downwind receptor(s) despite these existing controls, but that State believes it has no outstanding good neighbor obligations, the EPA expects the State to provide sufficient justification to support a conclusion that the State has adequate provisions prohibiting “any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will” “contribute significantly to nonattainment in, or interfere with maintenance by,” any other State with respect to the NAAQS. *See* CAA section 110(a)(2)(D)(i)(I). While the EPA has not prescribed a particular method for this assessment, the EPA expects states at a minimum to present a sufficient technical evaluation. This would typically include information on emissions sources, applicable control technologies, emissions reductions, costs, cost-effectiveness, and downwind air quality impacts of the estimated reductions, before concluding that no additional emissions controls should be required.⁶⁶

As explained in section III.A. in this document, the EPA and states must give independent significance to Prong 1 (significant contribution to nonattainment) and Prong 2 (interference with maintenance) when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).⁶⁷ The EPA gives effect to Prong 2 through identifying receptors that may have trouble attaining the NAAQS under varying air quality and meteorological conditions. *EME Homer City* upheld the EPA’s approach to using cost to determine “amounts” with respect to both Prong 1 and 2. *EPA v. EME Homer City Generation*, 572 U.S. at 518–520. The EPA’s use of the term “significant contribution” in its analysis at the third step of the 4-step interstate transport framework is applied for both Prongs 1 and 2. This approach to giving effect to the “interfere with maintenance” prong has been upheld

twice by the D.C. Circuit. *See EME Homer City*, 795 F.3d at 136; *Wisconsin*, 938 F.3d at 325–27. In effect, the EPA’s determination of what level of upwind contribution constitutes “interference” with a maintenance receptor is the same determination as what constitutes “significant contribution” for a nonattainment receptor. Nonetheless, this continues to give independent effect to Prong 2 because the EPA applies a broader definition for identifying maintenance receptors, which accounts for the possibility of problems maintaining the NAAQS under realistic potential future conditions. While the EPA and others may occasionally use the language of “significance” as a shorthand for determinations at the third step under both Prongs 1 and 2, this does not detract from the fact that the EPA gives Prong 2 independent effect under the 4-step interstate transport framework. Alternative approaches to defining and prohibiting emissions that “interfere with maintenance” must be, like the EPA’s approach, legally and technically justified and give effect to the language of the statute in a manner that ensures states’ good neighbor obligations are defined in a consistent and equitable manner.

As explained in section IV.B. and V.A. of this document, no states whose SIP submissions the EPA is proposing to partially disapprove in this action conducted an adequate analysis at Step 3, following either the EPA’s approach or an alternative approach. As explained in section I.A. of this document and further detailed in section VI. of this document, the EPA is proposing to apply the same Step 3 analysis and methodology completed in the Federal Good Neighbor Plan for 23 states to the additional states of Arizona, Iowa, Kansas, New Mexico, and Tennessee. The EPA’s approach to Step 3 is explained in section III.B.1.c. of the Federal Good Neighbor Plan.⁶⁸

5. Step 4 of the 4-Step Interstate Transport Framework

At Step 4, states (or the EPA) develop permanent and federally-enforceable control strategies to achieve the emissions reductions determined to be necessary at Step 3 to eliminate significant contribution to nonattainment or interference with maintenance of the NAAQS, as necessary to comply with the terms of the good neighbor provision requiring that SIPs (or FIPs) “contain adequate provisions prohibiting” such emissions. 88 FR at 9343. These control strategies

⁶⁶ As examples of general approaches for how such an analysis could be conducted for their sources, states could look to the CSAPR Update, 81 FR 74504, 74539–51; CSAPR, 76 FR 48208, 48246–63; CAIR, 70 FR 25162, 25195–229; or the NO_x SIP Call, 63 FR 57356, 57399–405. *See also* Revised CSAPR Update, 86 FR 23054, 23086–23116. Consistently across these rulemakings, the EPA has developed emissions inventories, analyzed different levels of control stringency at different cost thresholds, and assessed resulting downwind air quality improvements.

⁶⁷ *See North Carolina v. EPA*, 531 F.3d 896, 909–11 (D.C. Cir. 2008).

⁶⁸ 88 FR 36654, at 36678.

must be included in the State's SIP so that they are made permanent and federally enforceable. *See* CAA section 110(a)(2)(D) ("Each such [SIP] shall . . . contain adequate provisions—prohibiting . . ."). *See also* CAA section 110(a)(2)(A); *Committee for a Better Arvin v. EPA*, 786 F.3d 1169, 1175–76 (9th Cir. 2015) (holding that measures relied on by a State to meet CAA requirements must be included in the SIP submission).

As with the previous steps of the framework, as explained in section I.A. of this document and further detailed in section VII. of this document, in proposing FIPs for Arizona, Iowa, Kansas, New Mexico, and Tennessee, the EPA is proposing to implement necessary emissions reductions through the same set of permanent and enforceable measures promulgated for 23 other states in the Federal Good Neighbor Plan. The EPA's approach to Step 4 is explained in section III.B.1.d. of the Federal Good Neighbor Plan.⁶⁹

IV. SIP Submissions Addressing Interstate Transport of Air Pollution for the 2015 8-Hour Ozone NAAQS

A. SIP Summaries

1. Arizona

On September 24, 2018, the Arizona Department of Environmental Quality (ADEQ) submitted to the EPA the "Arizona State Implementation Plan Revision under Clean Air Act Sections 110(a)(1) and 110(a)(2) for the 2015 Ozone National Ambient Air Quality Standards" ("Arizona's 2018 SIP Submission"). Arizona's 2018 SIP Submission addresses the "infrastructure" requirements of CAA section 110(a)(2), including the good neighbor provisions under CAA section 110(a)(2)(D)(i)(I), for the 2015 ozone NAAQS.⁷⁰

Arizona's 2018 SIP Submission describes the 4-step interstate transport framework established by the EPA to address the good neighbor provision.⁷¹ Arizona references the results of the ozone modeling completed by the EPA using CAMx version 6.40 and 2011 base year, made available in the March 2018 memorandum, to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the State at

Steps 1 and 2 of the 4-step interstate transport framework. Arizona noted that the modeling results cited in the March 2018 memorandum demonstrate that Arizona is not shown to contribute greater than 1 percent of the NAAQS (*i.e.*, 0.70 ppb) to any of the modeled nonattainment or maintenance receptors in other states.⁷² Despite asserting that "Arizona still maintains that the one percent threshold is poorly suited for determining contribution obligations in the Southwestern US," Arizona relies on the contribution threshold of 1 percent of the NAAQS at Step 2.⁷³ Based on the model results cited in Arizona's 2018 iSIP Submission, Arizona finds that it does not contribute significantly to nonattainment or maintenance receptors in other states and that it is not necessary to identify emissions reductions or adopt any permanent or enforceable controls under the interstate transport provision for the 2015 ozone NAAQS.⁷⁴ Arizona also asserts that the Arizona SIP contains adequate provisions to ensure that air emissions in Arizona will not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other State in the future.⁷⁵

Prior Notices Related to Arizona's SIP Submission

On June 24, 2022, the EPA proposed to approve Arizona's 2018 iSIP Submission as meeting the good neighbor provision for the 2015 ozone NAAQS.⁷⁶ Our proposed approval was based upon the conclusion that Arizona was not linked to any downwind nonattainment or maintenance receptors, which was supported by the 2016v2 modeling described in the notice of proposed rulemaking for the proposed approval.⁷⁷ In response to that proposed rulemaking, the EPA received one comment letter providing evidence to suggest that Arizona likely contributes significantly to interstate ozone pollution. The commenter alleged that the 2016v2 modeling arbitrarily omits Arizona contributions to monitors in El Paso County, Texas, and Doña Ana County, New Mexico, and that Arizona is likely to significantly contribute to ozone concentrations at these receptors. The commenter also incorporated by reference comments that the commenter submitted in response to the EPA's April 6, 2022, proposed FIP addressing

regional ozone transport for the 2015 ozone NAAQS, identifying additional alleged flaws and omissions in the 2016v2 modeling.⁷⁸

As described in section III.B. of this document, the EPA constructed its 2016v3 emissions platform to update ozone transport modeling in response to these and similar comments received on the 2016v2 modeling and to develop the 2016v3 air quality modeling. The EPA also recognized that monitoring data for 2021 and 2022 supported recognizing additional, violating-monitor receptors. The EPA used this updated air quality analysis to inform its final Disapproval and Federal Good Neighbor Plan actions.⁷⁹ As described later in section IV.B.1. of this document, the 2016v3 modeling and violating-monitor receptor methodology identifies Arizona's maximum contribution to numerous downwind maintenance receptors to be greater than 1 percent of the standard (*i.e.*, greater than 0.70 ppb). Because the latest available modeling indicates that Arizona is linked to downwind maintenance receptors, the EPA is now withdrawing its 2022 proposed approval of Arizona's 2018 SIP Submission with respect to CAA section 110(a)(2)(d)(i)(I).

2. New Mexico

The EPA made a finding in 2019 that New Mexico had failed to submit a complete good neighbor SIP submission. *See* 84 FR 66612 (December 4, 2019). This triggered the EPA's obligation to promulgate a FIP for New Mexico within 2 years. When the EPA failed to do so, multiple parties brought deadline-suit litigation against the Agency. This resulted in a consent decree deadline of June 1, 2024, to either promulgate a FIP for New Mexico or approve a SIP submission fully resolving New Mexico's good neighbor obligations. *WildEarth Guardians v. Regan*, No. 22-cv-00174-RB-GBW (D.N.M. Aug. 16, 2022); *Sierra Club v. Regan*, No. 3:22-cv-01992-JD (N.D. Cal. Jan. 24, 2023). By stipulation of the parties, that deadline has now been extended to August 30, 2024. The EPA's duty to promulgate a FIP for New

⁷⁸ 87 FR 20036 (April 6, 2022).

⁷⁹ "Air Plan Disapprovals; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards," 88 FR 9336 (February 13, 2023), and "Federal 'Good Neighbor Plan' for the 2015 Ozone National Ambient Air Quality Standards," 88 FR 36654 (June 5, 2023).

⁸⁰ Details on the 2016v3 air quality modeling and the methods for projecting design values and determining contributions in 2023 and 2026 are described in the TSD titled "Air Quality Modeling Final Rule TSD—2015 Ozone NAAQS Good Neighbor Plan," hereafter known as the Final Good Neighbor Plan AQM TSD.

⁶⁹ 88 FR 36654, at 36684.

⁷⁰ Letter dated September 24, 2018, from Timothy S. Franquist, Director, Air Quality Division, ADEQ, to Michael Stoker, Regional Administrator, EPA Region IX, Subject: "Submittal of the Arizona State Implementation Plan Revision under Clean Air Act sections 110(a)(1) and 110(a)(2) for the 2015 Ozone NAAQS."

⁷¹ Arizona's 2018 SIP submission, 12.

⁷² *Id.* at 13.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 14.

⁷⁶ 87 FR 37776 (June 24, 2022).

⁷⁷ 87 FR 37776, 37782.

Mexico can only be suspended by the approval of a SIP submission. As discussed in section IV.B. of this document, the EPA proposes to disapprove the SIP submission New Mexico subsequently submitted, described below. This disapproval, if finalized, would not alter or reset the EPA's pre-existing obligation to promulgate a FIP for New Mexico.

On July 27, 2021, the New Mexico Environment Department (NMED) submitted a SIP submission certifying that the State's SIP satisfies requirements of interstate transport of air pollution for the 2015 ozone NAAQS. On June 9, 2021, on behalf of the City of Albuquerque Environmental Health Department (EHD), the Cabinet Secretary of NMED submitted to the EPA a certification that Albuquerque-Bernalillo County, and New Mexico as a whole, "does not cause or contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state."⁸¹ NMED and EHD's submission contained what NMED characterized as a weight of evidence analysis of New Mexico's contribution to ozone transport receptors using the data provided in the EPA's modeling results included as an attachment to the March 2018 memorandum. New Mexico did not explicitly follow the 4-step interstate transport framework but did examine downwind air quality and New Mexico's contributions using the analytic year of 2023 to describe New Mexico's linkages to receptors. On July 5, 2023, NMED submitted a supplemental letter containing Exhibit A, for the EPA's consideration in the Agency's review of the NMED and EHD SIP submissions. The following sections describe NMED and EHD's submissions, including Exhibit A, and the information provided for each step in the process.

a. Information Provided by New Mexico Regarding Step 1

For Step 1 of the 4-step interstate transport framework, NMED and EHD SIP submissions relied on the EPA's interstate transport modeling results that are included as an attachment to the March 2018 memorandum.⁸² These EPA modeling results, using a 2011 base year, provided: (1) projected average design value and maximum design value for 2023 for ozone monitors to identify nonattainment or maintenance receptors and (2) projected average contribution from State emissions to the

projected ozone concentrations at each ozone monitor to identify upwind state-to-downwind receptor linkages.

b. Information Provided by New Mexico Regarding Step 2

NMED and EHD's submission presented New Mexico's projected 2023 ozone contributions to maintenance and nonattainment receptors using the projections from the EPA's March 2018 memorandum. The State agencies state that in past rulemakings, the EPA has relied upon the 1 percent of the 2015 ozone NAAQS standard (0.70 ppb) contribution threshold when evaluating if an upwind State has a "potentially significant contribution to nonattainment or interference with maintenance"⁸³ impacts air quality in a downwind state. New Mexico began their Step 2 analysis by using the EPA's 1 percent threshold to evaluate contribution and identified that the State contributes 1 percent or more of the NAAQS to one maintenance receptor: Weld County Tower, Colorado (Monitor ID: 081230009), and one nonattainment receptor, Rocky Flats-N, Colorado (Monitor ID: 080590006).⁸⁴ ⁸⁵ Additionally, the EPA's March 2018 memorandum modeling indicated that upwind states contribute roughly 8 and 10 percent of the modeled 2023 design value at the Weld County receptor and the Rocky Flats-N receptor, respectively.

However, NMED and EHD argue that New Mexico does not contribute significantly to nonattainment or interfere with maintenance at the Weld County Tower and Rocky Flats-N receptors. NMED and EHD assert that a "weight of evidence" analysis is more appropriate than relying on a single, national standard for identifying linkages and determining whether contributions from an upwind State are significant. NMED and EHD believe that New Mexico should not be linked to Colorado receptors in the EPA's transport Step 2 analysis because the majority of the contribution to these receptors comes directly from Colorado. NMED and EHD attempt to justify this position by relying on a previous transport rulemaking that determined certain monitoring sites in California were not interstate transport receptors. Specifically, New Mexico references the approval of Arizona's 2008 ozone transport SIP submission, *see* 81 FR 31513. In that action, the EPA determined that Arizona did not significantly contribute to two California monitoring sites despite

contributing more than 1 percent of the NAAQS, because the EPA found the total collective contribution from all upwind states was so low at these sites that they need not be considered transport receptors. New Mexico attempts to expand the application of the EPA's reasoning in the Arizona action, asserting it would also be appropriate not to link New Mexico, or the other linked upwind states, to the Colorado receptors at the 1 percent threshold.

NMED and EHD's submission also claims that the relative share of in-state versus out-of-state contribution in Colorado, topographical influences on the transport of ozone in Colorado, and other air quality information support its "weight-of-evidence" analysis. To identify the portion of ozone levels in Colorado coming from in-state emissions as opposed to upwind-state emissions, New Mexico relied on the EPA's 2018 memorandum modeling data. Based on this data, NMED and EHD determined in-state emissions outweighed the portion of emissions coming from upwind states collectively.

NMED and EHD considered the topological influences on ozone concentrations in the Denver area based on information prepared by Colorado to support the final 2015 ozone NAAQS designation of the Denver area.⁸⁶ NMED and EHD assert in their submissions that the receptors in Colorado are predominantly impacted from local sources and thus the minimal contributions from upwind states do not warrant further controls in New Mexico. They contend that the topography of the Denver nonattainment area (NAA) disproportionately favors the formation of ozone due to local emissions. As support for their argument, NMED and EHD point to the EPA's TSD supporting the designation of the Denver NAA: "The three key circulation patterns (drainage flow, upslope flow, and mountain-plains solenoid circulation), in conjunction with the surface topography, in the [Denver] area serve to trap emissions and produce ozone in the basin formed by the surrounding higher elevation features. Further, these circulation patterns serve to recirculate prior day emissions into the Denver area population centers as the mountain-plains solenoid flow lifts the polluted atmosphere up the mountain slopes of the Rocky Mountains to the west in warm afternoons, and then returns the polluted air to the surface as the lofted air circulates back to the east and

⁸¹ *See* EHD SIP submission, attachment B, page 3.

⁸² As explained in section IV.A.2.c., NMED's Exhibit A acknowledged the EPA's 2016v3 modeling results and linkages.

⁸³ EHD's SIP submission Attachment B, page 7.

⁸⁴ *Id.* at Table 1, page 4.

⁸⁵ *Id.* at page 5.

⁸⁶ *Id.* at page 17. *See also* 83 FR 25776 (June 4, 2018).

subsidies overnight.”⁸⁷ New Mexico presents this information to further support their claim that the Denver NAA is significantly more impacted by emissions from within Colorado than from interstate transport.

NMED and EHD’s final weight of evidence factor consisted of an assessment of ozone air quality monitoring data and design values. Here, they identify downward trends in ozone precursor emissions (NO_x and VOC) from 2005 to 2018. NMED and EHD cite New Mexico’s current on-the-books rules as sufficient to resolve the State’s transport responsibilities and as reason to believe downward trends in emissions and ozone concentrations at the receptors for which they contribute greater than 0.70 ppb (Rock Flats-N and Well County Tower monitors) will continue to decrease. NMED included data on an overall trend of slightly increasing VOC emissions and decreasing NO_x emissions in New Mexico, Utah, Wyoming, California, and Texas from 2002 to 2014. New Mexico also provided data exhibiting a decrease of VOC and NO_x emissions from Colorado during the same time period. New Mexico credited the downward emissions trends to permanent and enforceable control measures. New Mexico made an argument that overall decreasing ozone concentrations and emissions trends in the state, and other upwind states, correlate with reduced contributions to nonattainment and maintenance receptors outside of New Mexico. NMED and EHD concluded that decreasing ambient ozone concentrations in Colorado is indicative of New Mexico contributing less to ozone in downwind states as time goes on.

This concluded New Mexico’s analysis in its original submission. New Mexico did not conduct an analysis of emissions-control opportunities within the State at Step 3. NMED and EHD concluded it would be unreasonable for New Mexico to take further actions to address its obligations under the good neighbor provisions for the ozone NAAQS. Thus, at Step 4, NMED and EHD determined that no additional permanent and enforceable measures were necessary to reduce the State’s emissions.

c. New Mexico Letter

On July 5, 2023, NMED submitted for the EPA’s consideration a letter with an attachment, Exhibit A. The letter indicates its submission is in response to the EPA’s indication that it may

disapprove New Mexico’s SIP submission. To the EPA’s awareness, this letter was not subject to public notice or rulemaking process at the State level and does not in itself purport to be a SIP submission or a revision to New Mexico’s SIP. As such, the EPA takes the information in the letter under advisement but does not consider this letter to be a new SIP submission in its own right or part of the SIP submission dated July 27, 2021.

In its letter, NMED asserts the EPA should account for emissions reductions that have occurred since 2020 that could resolve the State’s transport obligations. NMED identified emissions reductions from two current compliance orders that resulted in a reduction of 236 tons of annual NO_x emissions. NMED entered into a settlement agreement with ETC Texas Pipeline Ltd (ETC) for its Jal #3 plant, compliance order No. AQB 20–63, which was lodged on August 25, 2021. The settlement agreement mandated that the facility remove its sulfur recovery unit, which resulted in an emissions reduction of 4.8 tons of NO_x per year. Additionally, NMED entered into a consent decree with ETC for its Eunice Gas Plant, compliance order No. AQB 20–64, which was lodged on September 9, 2021. The consent decree required the shutdown of the Eunice plant, except for Amanda Booster Station, resulting in emissions decrease of 231.4 tons of NO_x per year. Lastly, NMED references emissions reductions anticipated from the consent decree lodged with Matador Production Company, filed on March 27, 2023. NMED is anticipating emissions reductions of a total 77 tons of NO_x over 3 years and to occur before 2030.

NMED argues that the emissions reductions resulting from these compliance orders are satisfactory to fulfil the emissions reductions that would occur under the Federal Good Neighbor Plan for the 2015 Ozone Standard. NMED states that based on the formula applied under the Federal Good Neighbor Plan, the EPA identified 30 tons of emissions reductions achievable in 2023 under the current formula for EGU emissions reductions.⁸⁸ NMED claims that the “EPA indicated that this 30 ton per year reduction would be all that is necessary to meet its good neighbor FIP requirements.”⁸⁹ NMED argues that as the NO_x emissions decreases outlined in the provided consent decrees are

greater than the emissions reductions anticipated in the Federal Good Neighbor Plan, the State will have met its obligations for interstate transport.

3. Tennessee

On September 13, 2018, Tennessee submitted a SIP revision addressing the CAA section 110(a)(2)(D)(i)(I) interstate transport requirements for the 2015 8-hour ozone NAAQS.^{90,91} The SIP submission provided Tennessee’s analysis of its impact to downwind states and concluded that emissions from the State will not significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other states. Tennessee’s submission relied on the EPA’s modeling results for 2023 using a 2011 base year, contained in the March 2018, memorandum, to identify downwind nonattainment and maintenance receptors that may be impacted by emissions from sources in the State at Steps 1 and 2 of the 4-step interstate transport framework.⁹² The Tennessee Department of Environmental Control (TDEC) reviewed the EPA’s 2023 modeling, concurred with the results, and determined that the EPA’s future year projections were reasonable and account for source shutdowns, new controls, and fuel switches. TDEC summarized the State’s upwind contribution to 26 nonattainment and maintenance receptors and noted that according to the modeling, Tennessee’s largest impact on any potential downwind receptor in 2023 would be 0.31 ppb to a nonattainment receptor and 0.65 ppb to a maintenance receptor. Tennessee concluded that emissions from Tennessee do not contribute above 1 percent of the NAAQS or above 1 ppb at any receptors.

Tennessee’s submission asserted that NO_x emissions are considered the primary cause of formation of ozone in the southeast United States, and emphasized a significant reduction in NO_x emissions reductions from coal-fired EGUs and other large NO_x sources leading to improvements in air quality, including reductions attributable to

⁹⁰ The September 13, 2019, SIP submission provided by TDEC was received by the EPA on September 17, 2018.

⁹¹ On September 18, 2018, Tennessee submitted multiple SIP revisions under one cover letter. The EPA is only acting on Tennessee’s 2015 ozone good neighbor interstate transport SIP requirements in this document.

⁹² The EPA notes that Tennessee’s SIP submission is not organized around the EPA’s 4-step interstate transport framework for assessing good neighbor obligations, but the EPA summarizes the submission using that framework for clarity here.

⁸⁷ See https://www.epa.gov/sites/default/files/2018-05/documents/co_tsd_final_0.pdf.

⁸⁸ *Ozone Transport Policy Analysis Final Rule Technical Support Document*, Table B–3. 2024 Ozone Season NO_x Emissions for States at Different Uniform Control Scenarios.

⁸⁹ NMED’s July 5, 2023, letter to the EPA, at 1.

previous transport rulemakings.⁹³ Additionally, TDEC identifies existing SIP-approved provisions, Federal regulations and programs, court settlements, and statewide source shutdowns that TDEC believes limit ozone precursor emissions in the State.⁹⁴

Based on the information contained in Tennessee's transport SIP submission, TDEC concluded that Tennessee does not significantly contribute to nonattainment or interfere with maintenance in another State of the 2015 8-hour ozone NAAQS, and that the SIP submission provides for adequate measures to control ozone precursor emissions.

Prior Notices Related to Tennessee's SIP Submission

Previously, the EPA proposed approval of Tennessee's September 13, 2018, SIP submission, based on the contribution modeling provided in the March 2018 memorandum. *See* 84 FR 71854 (December 30, 2019). When the EPA completed updated modeling of the 2023 analytic year in 2020 using a 2016-based emissions modeling platform (2016v1), however, it became evident that Tennessee was projected to be linked to downwind nonattainment and maintenance receptors.⁹⁵ As a result, the EPA did not act on Tennessee's SIP submission when it published a supplemental proposal in 2021 to approve four other southeastern states' good neighbor SIP submissions, using the updated 2023 modeling. *See* 86 FR 37942, 37943 (July 19, 2021).

The 2016v2 modeling comported with the 2016v1 modeling results for Tennessee, in that it continued to show Tennessee was linked to at least one downwind-maintenance-only receptor in 2023. Based on this information and the EPA's evaluation of the information and arguments put forward by the State in its submission, the EPA withdrew its December 30, 2019, proposed approval of Tennessee's September 13, 2018,

interstate transport SIP submission, and the EPA proposed disapproval of Tennessee's submission. *See* 87 FR 9545 (February 22, 2022).

As described in section III.C. of this document, the EPA received numerous comments on the 2016v2 modeling used in its proposed ozone transport actions, including its proposed disapproval of Tennessee's submission. The EPA incorporated this feedback and made several updates to the 2016v2 inventories and model design to construct a 2016v3 emissions platform, which the EPA used to develop the 2016v3 air quality modeling. The EPA used the 2016v3 modeling to support the final action on 21 interstate transport SIP submissions for the 2015 ozone NAAQS.⁹⁶ The Agency also found there were additional receptors that would struggle to attain or maintain the NAAQS in 2023, which it identified as violating-monitor receptors. The final air quality analysis modeling indicated that while Tennessee was no longer projected in the modeling to be linked to any nonattainment or maintenance receptors, the State was linked above 1 percent of the NAAQS to five violating-monitor receptors, all located in Texas. *See* 2016v3 AQM TSD, at C-5.

Although the EPA identified a linkage between emissions in Tennessee and violating-monitor receptors, in recognition that it had not included such receptors in its proposed action, the EPA did not take final action on Tennessee's transport SIP submission at that time. The EPA is now withdrawing its proposed disapproval of Tennessee's September 13, 2018, interstate transport SIP submission as published on February 22, 2022, at 87 FR 9545.

B. EPA Evaluation

The EPA is proposing to find that SIP submissions from Arizona, New Mexico, and Tennessee meet the states' obligations with respect to Prong 1, prohibiting emissions that contribute significantly to nonattainment of the 2015 8-hour ozone NAAQS, but do not meet obligations with respect to Prong 2, interference with maintenance of the 2015 8-hour ozone NAAQS in any other state. This proposal is based on the EPA's evaluation of each State's SIP submission, considered in light of the state-of-the-science 2016v3 modeling for

2023 and 2026, the certified ozone monitoring data and design values for 2021 and 2022, and corresponding contribution analysis. Therefore, the EPA is proposing to partially approve with respect to Prong 1 and partially disapprove with respect to Prong 2 the SIP submissions from Arizona, New Mexico, and Tennessee.

1. Arizona

a. Evaluation of Information Provided by Arizona Regarding Steps 1 and 2

In Arizona's 2018 SIP Submission, the State cites the EPA modeling released in the March 2018 memorandum to conclude that Arizona does not contribute significantly (*i.e.*, equal to or above the 0.70 ppb threshold) to any nonattainment or maintenance receptor in another state.⁹⁸ In this proposal, the EPA relies on the Agency's 2016v3 modeling, which uses a more recent base year and more up-to-date emissions inventories, compared to the modeling that was released in the March 2018 memo. The 2016v3 modeling along with the violating-monitor receptor methodology are used to identify downwind receptors, calculate upwind contributions, and determine "linkages" to downwind air quality problems in 2023 using the 0.70 ppb threshold (*i.e.*, 1 percent of the NAAQS). As shown in Tables IV.B-1-3, the updated EPA contribution modeling identifies Arizona's maximum contribution to a downwind nonattainment or maintenance receptor to be greater than 1 percent of the standard (*i.e.*, greater than 0.70 ppb). Because the entire technical basis for Arizona's determination with respect to CAA section 110(a)(2)(D)(i)(I) in its 2018 SIP Submission is that Arizona is not linked at Step 2, the EPA proposes to partially disapprove Arizona's SIP submission with respect to Prong 2, interference with maintenance, based on the EPA's finding that such a linkage does exist to maintenance-only receptors.

b. Results of the EPA's Step 1 and Step 2 Modeling and Findings for Arizona

As described in section III.B. of this document, the EPA performed air quality modeling using the 2016v3 emissions platform to project design values and contributions for 2023 and 2026. These data were examined to determine if Arizona contributes at or above the threshold of 1 percent of the 2015 ozone NAAQS (0.70 ppb) to any downwind nonattainment or maintenance receptor. As shown in Table IV.B-1, the data indicate that, in

⁹³ The Tennessee SIP revision specifically cites the NO_x Budget Trading Program, CAIR, and CSAPR. In addition, the Tennessee SIP revision discusses Tennessee rule 1200-03-27-.12 (NO_x SIP Call requirements for Stationary Boilers and Combustion Turbines), which had not been approved into the SIP at the time of the September 13, 2018, submission. The EPA finalized approval of TAPR 1200-03-27-.12 into the Tennessee SIP on March 2, 2021. *See* 86 FR 12092.

⁹⁴ *See* page 9 through 12 of Tennessee's September 13, 2018, SIP submission for a list of SIP-approved State rules and Federal rules. This can be found in Docket No. EPA-R04-OAR-2021-0841.

⁹⁵ *See* "Air Quality Modeling Technical Support Document for the Final Revised Cross-State Air Pollution Rule Update", available in Docket ID No. EPA-HQ-OAR-2021-0663.

⁹⁶ Disapproval Action, 88 FR 9336 (February 13, 2023), and Federal Good Neighbor Plan, 88 FR 36654 (June 5, 2023).

⁹⁷ Details on the 2016v3 air quality modeling and the methods for projecting design values and determining contributions in 2023 and 2026 are described in the TSD titled "Air Quality Modeling Final Rule TSD—2015 Ozone NAAQS Good Neighbor Plan," hereafter known as the Final Good Neighbor Plan AQM TSD.

⁹⁸ Arizona's 2018 iSIP submission, 13-14.

2023, emissions from Arizona contribute greater than 1 percent of the 2015 ozone NAAQS to six maintenance-only receptors in Colorado, Nevada, New Mexico, and Texas.⁹⁹ Table IV.B.1–3 indicates that in 2023, emissions from Arizona contribute greater than 1 percent of the NAAQS to three violating-monitor maintenance-only

receptors in Nevada and New Mexico. Furthermore, data for 2026 in Table IV.B.1–2 indicate that emissions from Arizona contribute greater than 1 percent of the 2015 ozone NAAQS to five maintenance-only receptors in Colorado and New Mexico.¹⁰⁰ In addition, Arizona's contribution exceeds 1 ppb at five receptors in 2023

and two receptors in 2026. Thus, whether Arizona could have sought to justify an alternative 1 ppb threshold is irrelevant to EPA's determination that Arizona is linked, as Arizona's contributions to receptors exceed even that higher alternative contribution threshold.

TABLE IV.B.1–1—ARIZONA LINKAGE RESULTS BASED ON THE EPA UPDATED 2023 MODELING

Receptor ID	Location	Nonattainment/maintenance	2023 Average design value (ppb)	2023 Maximum design value (ppb)	Arizona contribution (ppb)
80690011	Larimer, Colorado	Maintenance-Only	70.9	72.1	0.86
350130021	Doña Ana, New Mexico	Maintenance-Only	70.8	72.1	1.04
350130022	Doña Ana, New Mexico	Maintenance-Only	69.7	72.4	1.06
350151005	Eddy, New Mexico	Maintenance-Only	69.7	74.1	1.34
350250008	Lea, New Mexico	Maintenance-Only	69.8	72.2	1.66
481410037	El Paso, Texas	Maintenance-Only	69.8	71.4	1.69

Source: Final Good Neighbor Plan AQM TSD.

TABLE IV.B.1–2—ARIZONA LINKAGE RESULTS BASED ON THE EPA UPDATED 2026 MODELING

Receptor ID	Location	Nonattainment/maintenance	2026 Average design value (ppb)	2026 Maximum design value (ppb)	Arizona contribution (ppb)
80690011	Larimer, Colorado	Maintenance-Only	70.0	71.2	0.71
350130021	Doña Ana, New Mexico	Maintenance-Only	69.9	71.2	0.82
350130022	Doña Ana, New Mexico	Maintenance-Only	69.0	71.6	0.82
350151005	Eddy, New Mexico	Maintenance-Only	69.1	73.4	1.06
350250008	Lea, New Mexico	Maintenance-Only	69.2	71.6	1.34

Source: Final Good Neighbor Plan AQM TSD.

TABLE IV.B.1–3—ARIZONA 2023 LINKAGE RESULTS BASED ON VIOLATING-MONITOR MAINTENANCE-ONLY RECEPTORS

Receptor ID	Location	2021 Design value (ppb)	2022 Design value (ppb)	2021 4th high (ppb)	2022 4th high (ppb)	Arizona contribution (ppb)
320030043	Clark, Nevada	73	75	74	74	0.77
350011012	Bernalillo, New Mexico	72	73	76	74	1.62
350130008	Doña Ana, New Mexico	76	71	79	78	1.13

Source: Final Good Neighbor Plan AQM TSD.

Therefore, based on the EPA's evaluation of the information submitted by Arizona, and based on the EPA's most recent modeling results for 2023 and 2026 using the 2016v3 emissions platform, the EPA proposes to find that Arizona is not linked to any nonattainment receptor. However, the EPA finds that Arizona is linked at Steps 1 and 2 to at least one, and in fact several, maintenance-only receptors, based on the available analytical information, which includes the modeling results from the 2016v3 platform and the violating-monitor receptor analysis.

c. Evaluation of Information Provided Regarding Step 3

To determine what, if any, emissions significantly contribute to nonattainment or interfere with maintenance and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I), at Step 3 of the 4-step interstate transport framework, a state's emissions are further evaluated, in light of multiple factors, including air quality and cost considerations. The EPA recognizes that the modeling results released with the March 2018 memorandum indicated Arizona would not contribute at or above 1 percent of the NAAQS to any downwind receptor.

Arizona's 2018 SIP Submission therefore concluded that it was not necessary to identify any emissions reductions or adopt any permanent and enforceable controls to meet the good neighbor provision for the 2015 ozone NAAQS.¹⁰¹ Arizona's 2018 SIP Submission states that "Arizona believes that this SIP contains adequate provisions to ensure that air emissions in Arizona do not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other State in the future."¹⁰²

However, as discussed previously in this section, the EPA's more recent air quality analysis for 2023 and 2026

⁹⁹ Final Good Neighbor Plan AQM TSD, Appendix C, available in Docket ID No EPA–HQ–OAR–2021–0668.

¹⁰⁰ *Id.*

¹⁰¹ Arizona's 2018 iSIP Submission, 13–14.

¹⁰² *Id.* at 14.

indicates that sources in Arizona are in fact contributing to downwind air quality problems at several maintenance-only receptors. Based on this record, the EPA finds the State's conclusion that its SIP contains adequate provisions prohibiting emissions interfering with maintenance of the 2015 ozone NAAQS in other states to lack justification, and the EPA proposes to partially disapprove the submission.

d. Conclusion

For the reasons described in this section, the EPA proposes to partially approve Arizona's SIP submission with respect to Prong 1 of CAA section 110(a)(2)(D)(i)(I) and to partially disapprove Arizona's SIP submission with respect to Prong 2 of CAA section 110(a)(2)(D)(i)(I).

2. New Mexico

a. Evaluation of Information Provided by New Mexico Regarding Step 1

As noted earlier, NMED and EHD first relied on the modeling information from the EPA's March 2018 memorandum which used a 2011 base period with 2011 meteorology to identify nonattainment and maintenance receptors and upwind-state contribution levels at those receptors. NMED and EHD acknowledged that this modeling showed a linkage to one nonattainment and one maintenance-only receptor in the Denver area at or above 0.70 ppb. Since the time of the State's submission, the EPA updated the modeling to a 2016 base period with 2016 meteorology and updated emissions data to produce new 2023 model projections and released this new modeling in 2022 (commonly referred to as 2016v2 modeling platform). As explained in section III.C. of this document, in response to comments, the EPA further refined its modeling in the 2016v3 modeling platform, issued in 2023.¹⁰³ Under both the EPA's 2011-based modeling included in the March 2018 memorandum that New Mexico relied upon in their SIP submission and the EPA's updated 2016v3 modeling, there are receptors identified, to which New Mexico is linked above 1 percent of the NAAQS, as described in the next section.¹⁰⁴

¹⁰³ Air Quality Modeling Final Rule Technical Support Document—2015 Ozone NAAQS Good Neighbor Plan in Docket ID No. EPA-R08-OAR-2023-0375.

¹⁰⁴ The 2011 modeling relied on by NMED and EHD in the SIP submission identified linkages to one nonattainment receptor, the Rocky Flats-N receptor, and the one maintenance receptor, the Weld County Tower receptor, in 2023. See NMED SIP Submission at 4.

b. Evaluation of Information Provided by New Mexico Regarding Step 2

As in Step 1, NMED and EHD relied upon the modeling released in the EPA's March 2018 memo, and in its July 2023 letter, NMED relied on the EPA's 2016v3 modeling results to analyze projected contributions to downwind receptors. As explained in section IV.A.2. of this document, while NMED and EHD acknowledge the EPA's modeling results identifying a contribution greater than 0.70 ppb, the agencies do not find it appropriate to rely on a particular threshold (*i.e.*, 0.70 ppb) at Step 2 to determine whether a State is linked (or significantly contributing) to a downwind receptor in the West, but instead they rely on a weight of evidence approach. NMED and EHD point to the EPA's past approval of Arizona's 2008 ozone good neighbor SIP submission, in which the EPA approved Arizona's SIP based on an evaluation of receptors in California to support the use of a weight of evidence approach in evaluating interstate transport and claim that the EPA determined a weight of evidence approach to be an appropriate evaluation to apply in the West.¹⁰⁵

Although NMED and EHD's approach to evaluating whether an upwind State is linked to a downwind receptor differs from the EPA's broadly applied 4-step interstate transport framework by relying instead on a "weight of evidence" approach, here, we evaluate that "weight of evidence" methodology NMED has chosen to apply. While the NMED and EHD submission does not claim to establish a linkage, and instead postulates that it is inappropriate to apply a uniform standard to determine whether a State's contributions should be further evaluated in Step 3, the submission does rely on a 1 percent threshold to identify which receptors to apply a weight of evidence analysis. Therefore, while the NMED and EHD submission seems to disagree in principle with the use of a single threshold at Step 2, they have effectively moved to apply the same threshold for the same purpose the EPA would do at Step 2—rely on a 1 percent threshold to identify receptors to which a State is linked and therefore require further evaluation at Step 3 to determine whether any of the State's contributions, if any, are significant.

While the EPA does not disagree with the methodology NMED and EHD used in the submission to identify receptors where the State is linked, the EPA continues to find its 4-step interstate

transport framework to be an appropriate and nationally consistent approach to evaluating interstate transport, including the application of a contribution threshold at Step 2 of the framework. As stated in the EPA's final SIP disapproval action, the EPA disagrees with the NMED and EHD submission that neither its nationwide photochemical grid modeling nor the 4-step interstate transport framework for ozone can generally be applied to states in the western region of the U.S., including contributions from sources in New Mexico, and has maintained that position consistently throughout numerous actions.¹⁰⁶

The NMED and EHD submission cites the EPA's action on Arizona's 2008 ozone good neighbor SIP as evidence that the EPA relied on a weight of evidence approach when evaluating interstate transport in the West. In that action, the EPA considered the collective contribution from upwind states to monitoring sites in California as part of the basis for approval of the State's submission, despite linkages over 1 percent from Arizona to a select few California monitoring sites. The EPA disagrees that New Mexico's contribution to Colorado is comparable to the situation addressed in the Arizona 2008 ozone good neighbor action. The facts that supported the EPA's conclusion on Arizona's 2008 ozone good neighbor SIP were unique; in the Disapproval action and Federal Good Neighbor Plan, the EPA has already explained that it rejects that a comparable consideration is relevant for receptors in Colorado, which the EPA has consistently found are impacted by the collective contribution of numerous upwind states at levels that well exceed the circumstances of the California sites. See 88 FR at 9378–79 (western State policy generally); *id.* at 9360 (rejecting similar arguments in disapproving SIP submission from Utah); *see also* Response To Comments Document, EPA-HQ-OAR-2021-0663, at 236–237. At times the EPA has found it appropriate to examine more closely discrete issues for some western states;¹⁰⁷ however, the EPA has consistently applied the 4-step interstate transport framework in western states, as it proposes to do in this action, and

¹⁰⁶ For a discussion of this history, *see* for example 87 FR 31480–81 (proposed disapproval of Utah SIP submission) and 87 FR 31453–56 (proposed disapproval of California SIP submission).

¹⁰⁷ *See, e.g.*, 87 FR 61249, 61254–55 (October 11, 2022) (in approving Colorado's interstate transport SIP for the 2015 ozone NAAQS, analyzing unique issues associated with wintertime inversion conditions in certain western areas).

¹⁰⁵ NMED SIP submission at 5.

has previously identified ozone transport problems in the West, including in Colorado, that are similar to those in the east.¹⁰⁸

New Mexico claims that the Weld County Tower and Rocky Flats-N receptors are impacted by the same magnitude of contributions from interstate transport as the California receptors were in the approval of the Arizona transport SIP submission. This, however, is not represented in the data presented in NMED and EHD's submittals. Total upwind contributions were 10 percent and 8 percent of the projected 2023 design values at the Rocky Flats-N and Weld County Tower receptors, respectively, and five states were determined to be linked at or above 1 percent of the NAAQS. The results show that the upwind contributions to Colorado are significantly greater than the upwind contributions to the monitors evaluated in California when taking action on Arizona's 2008 ozone NAAQS SIP submission, where the total contribution from all upwind states was 2.5 percent and 4.4 percent of the total ozone concentration at the two monitoring sites in California to which Arizona contributed greater than 1 percent.

The determination made to remove the identified California receptors from the Step 1 analysis, done in the context of the less protective 2008 ozone NAAQS, was a narrow circumstance that does not apply in the vast majority of receptors outside of California. The data presented by New Mexico suggests the circumstances that led the EPA to remove California receptors from Step 1 do not apply to receptors in Colorado. In previous rulemakings, for example, the EPA has, in fact, determined that receptors in Colorado are heavily impacted by upwind-state contribution. *See, e.g.*, 82 FR 9155 (Feb. 3, 2017); 81 FR 71991 (October 19, 2016). The EPA affirms, contrary to NMED's assertion, that the Colorado receptors that NMED analyzed are impacted by upwind State contributions.¹⁰⁹ In fact, nowhere outside California do we project that there will be receptors having such a low total upwind contribution as is the case for California.¹¹⁰ Further, at the El Paso UTEP receptor (Monitor ID: 481410037) which, as shown in Table IV.B.2–1, is the receptor to which emissions from sources in New Mexico are linked, there are 2 states linked above 1 percent of the standard and 6

percent of the ozone design values is due to the collective contribution from upwind states.

c. Results of EPA's Step 1 and Step 2 Modeling and Findings for New Mexico

As described in section I. of this document, the EPA has performed updated air quality modeling using the 2016v3 emissions platform to project design values and contributions for 2023. These data were examined to determine if the newer modeling also indicated that New Mexico contributes at or above the threshold of 1 percent of the 2015 ozone NAAQS (0.70 ppb) to any downwind nonattainment or maintenance receptor. As shown in IV.B.2–1, the data¹¹¹ indicates that in 2023, emissions from New Mexico contribute greater than 1 percent of the standard to a maintenance-only receptor in El Paso, Texas.¹¹² New Mexico is not linked to any violating-monitor receptors in 2023. Based on the 2016v3 modeling, the average and maximum design values for the El Paso monitor in 2026 are below the level of the 2015 ozone NAAQS. In this regard, New Mexico is not projected to be linked to any receptors in 2026.

TABLE IV.B.2–1—NEW MEXICO LINKAGE RESULTS BASED ON THE EPA'S UPDATED 2016V3 2023 MODELING

Receptor ID	Location	Nonattainment/maintenance	2023 Average design value (ppb)	2023 Maximum design value (ppb)	New Mexico contribution (ppb)
481410037	El Paso, TX	Maintenance	69.8	71.4	1.59

Therefore, based on the EPA's evaluation of the information submitted by NMED and EHD, and based on the EPA's most recent modeling results for 2023 and 2026 using the 2016v3 emissions platform, the EPA proposes to find that New Mexico is not linked to a nonattainment receptor. However, the EPA finds that New Mexico is linked at Steps 1 and 2 to a maintenance-only receptor in 2023. Therefore, the EPA will proceed to evaluate NMED and EHD's SIP submission at Step 3 of the 4-step interstate transport framework as it pertains to Prong 2, interference with maintenance of the 2015 ozone NAAQS.

d. Evaluation of Information Provided Regarding Step 3

To determine what, if any, emissions significantly contribute to nonattainment or interfere with maintenance and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I), at Step 3 of the 4-step interstate transport framework, a state's emissions are further evaluated, in light of multiple factors, including air quality and cost considerations. NMED and EHD's initial SIP submission did not conduct an analysis of emissions control opportunities within the state, applying either the EPA's multifactor analysis at Step 3 or using any other framework of

analysis. Instead, the submission presents a three-part "weight of evidence" analysis to determine no reductions are needed beyond existing emissions reductions efforts to satisfy the State's obligations with regards to the good neighbor provision.

NMED's July 2023 letter uses mass-based emissions reductions identified on an ozone-season wide basis derived from the Step 3 (and Step 4 analysis for EGUs) completed by the EPA in the Federal Good Neighbor Plan to identify the magnitude of emissions that NMED assumes constitutes the identification of "significant contribution" that must be eliminated to address the State's good

¹⁰⁸ *See, e.g.*, 87 FR 31443, 31453–57 (May 24, 2022); 83 FR 65093, 65094 (December 19, 2018); 82 FR 9155, 9157 (February 3, 2017); 82 FR 9142, 9149–50 (February 3, 2017); 81 FR 74504, 74523 (October 26, 2016); 81 FR 71991, 71993–95 (October 19, 2016).

¹⁰⁹ Air Quality Modeling Final Rule Technical Support Document—2015 Ozone NAAQS Good Neighbor Plan in Docket ID No. EPA–HQ–OAR–2021–0668.

¹¹⁰ *See* 88 FR at 36718 regarding contribution to certain monitoring sites in California and its relation to the EPA's approval of Arizona's 2008 ozone NAAQS transport SIP submittal.

¹¹¹ Design values and contributions at individual monitoring sites nationwide are provide in the file: "2016v3 Final FIP DVs state contributions.xlsx" which is included in docket ID No. EPA–HQ–OAR–2021–0668.

¹¹² These modeling results are consistent with the results of a prior round of 2023 modeling using the

2016v1 emissions platform which became available to the public in the fall of 2020 in the Revised CSAPR Update, as noted in section I. of this document. That modeling showed that New Mexico had a maximum contribution greater than 0.70 ppb to at least one nonattainment or maintenance-only receptor in 2023. These modeling results are included in the file "Ozone Design Values And Contributions Revised CSAPR Update.xlsx" in docket ID No. EPA–HQ–OAR–2021–0663.

neighbor obligations. NMED's letter asserts that certain compliance orders entered in recent years would achieve an equivalent or greater amount of NO_x emissions reduction (on a mass-basis) than the Federal Good Neighbor Plan is projected to require from EGUs in New Mexico.

In this section, we evaluate the State's weight of evidence analysis submitted in the SIP submission, and then in the following section (Section IV.B.2.e of this document) address the argument put forward by NMED in the July 2023 letter.

As summarized in section IV.A.2. of this document, NMED and EHD's weight of evidence consisted of three parts, (1) a comparison of in-state emissions contributions and out-of-state contributions to the receptors with linkages from New Mexico, (2) consideration of topography and airflow associated with local ozone formation in the Denver area, and (3) an evaluation of trends in emissions and ozone concentrations at receptors with linkages and western states.

Regarding the first weight of evidence comparing in-state and out of State emissions, the EPA disagrees that these factors are sufficient to establish that New Mexico's emissions do not significantly contribute to receptors in any other state. While NMED and EHD point to a relatively higher level of contributions from non-anthropogenic, local, or international contributions in the West as reason for evaluating interstate transport differently in the West, a State is not excused from eliminating its significant contribution due to contributions from these sources, where the data show that anthropogenic emissions from upwind states also contribute to identified receptors at levels that indicate an interstate contribution problem as well. As stated in section V.C.2. of the EPA's final SIP Disapproval action, a State is not excused from eliminating its significant contribution on the basis that international emissions also contribute some amount of pollution to the same receptors to which the State is linked. This same principle applies broadly to other arguments as to which emissions are the "cause" of the problem; the good neighbor provision established a contribution standard, not a "but-for" causation standard. *See Wisconsin*, 938 F.3d at 323–25. The EPA's position on this issue is established in the SIP Disapproval action. *See* 88 FR at 9378 (rejecting this argument as to international contribution); Disapproval action RTC at 455–58 (rejecting this argument as to in-state contribution); *id.* at 459–62 (rejecting this argument as to

non-anthropogenic contribution). Nor did New Mexico offer a test or standard by which these considerations could be applied on a principled basis to establish when, if they were relevant considerations, they would justify a different approach for any particular state. New Mexico only argued that these considerations should excuse its own obligations.

The submission's second weight of evidence factor considers the Denver area's topography and air flow direction. The EPA has evaluated the information in the submission and proposes to determine that this evidence does not provide sufficient reason to support NMED and EHD submission's conclusion that the contributions from New Mexico to the receptors identified by the EPA's modeling is not significant. The NMED and EHD submission claims that the EPA had concluded that geographical features (mountains, etc.) in and around the Denver NAA "magnify and constrain the influence of local emissions on air quality" and ozone production by citing the EPA's description of the region in the EPA's designation of the Denver NAA for the 2015 ozone standard.

The EPA evaluated this argument thoroughly in the SIP Disapproval action. The EPA explained, despite the local geographical features in and around the Denver NAA substantial portion of the transport problem at these receptors, on the order of 6–10 percent (depending on individual receptor and modeling version used) is the result of transport from states outside of Colorado. The EPA evaluated the performance of its 2016v3 modeling in all areas of the country, including in Colorado and in the southwest (where New Mexico is linked to an El Paso receptor), and the Agency found the modeling performed within parameters and is reliable for use to inform determinations of contribution, even in areas of unique western topography. *See* RTC 171–184. These same findings hold true for New Mexico's linkage, whether assessed in relation to its contribution to Colorado receptors in the 2011-based modeling, or in the linkage to El Paso found in 2016v3 modeling.

The third weight of evidence provided in the SIP consists of monitoring data and emissions data to justify their conclusion that no additional emissions reductions would be necessary to satisfy New Mexico's ozone transport obligations.

The NMED and EHD submission points to a projected downward trend of ozone levels at monitors within the Colorado nonattainment area from 2008 to 2018, and VOC and NO_x emissions

reductions from 2002 to 2014 in states contributing above 1 percent of the NAAQS to the Weld County or Rocky Flats-N receptors. The submission did not quantify the total anticipated reductions in NO_x and VOC emissions from New Mexico's existing regulatory requirements nor did it evaluate the impact of those reductions in downwind air quality at the Denver area receptors to which New Mexico was projected to be linked in the 2011-based modeling. In general, the air quality modeling that the EPA has conducted already accounts for "on-the-books" emissions control measures, including the expected reductions those measures achieve through 2023. The 2016v3 modeling, which contains updated emissions inventories for New Mexico and other states, established a continued linkage from New Mexico to at least one downwind receptor in 2023 at Steps 1 and 2, despite emissions control efforts in the State.¹¹³ Applying the submission's same logic in this weight of evidence to the linkage identified in the EPA's 2016v3 modeling, the El Paso County, Texas, receptor, the EPA identifies a similar flaw. Because a linkage continues to occur under projected baseline emissions levels, the next analytical step would be to conduct an analysis of emissions control opportunities in the State to determine what, if any, emissions may constitute "significant contribution" and therefore should be prohibited. The EPA explained in the SIP Disapproval action that an alternative approach of simply relying on emissions trends data, without including those claimed reductions as enforceable control measures within a SIP, is insufficient. 88 FR at 9354, 9356, 9378–79; Response To Comments at 329–33. Similarly, emissions trends do not themselves provide a principled basis for determining what "amount" of emissions constitutes "significant contribution." *See* 88 FR at 9375–76.

Based on this evaluation of the weight of evidence analysis provided in NMED and EHD's SIP submission, the EPA finds that the analysis is insufficient to support the conclusion that the State

¹¹³ As the EPA explained in the final SIP Disapproval action, the EPA views changes in linkages between 2011-based meteorology and 2016-based meteorology not as an indication of uncertainty in whether a State is linked at Step 2 but rather as confirmation that the State's emissions are substantial enough to generate linkages under alternative meteorological data sets. As such, the changes in linkage observed between the 2011-based and 2016v3 modeling for New Mexico does not alter the EPA's findings or justify a less rigorous analysis at Step 3—just as the EPA found for many other states in connection with the Disapproval action. *See* 88 FR at 9367.

does not interfere with maintenance at receptors in other states. The EPA's updated air quality analysis indicates New Mexico is not linked to any nonattainment receptors but is linked to a maintenance-only receptor in El Paso, Texas. Thus, the EPA proposes partial disapproval of New Mexico's submission with respect to Prong 2.

e. NMED's July 2023 Letter

The EPA has considered the additional information New Mexico provided in its July 2023 letter. At the outset, we note that this letter did not undergo the requisite public rulemaking process at the State level, so the EPA does not consider it to be either a SIP submission itself or a supplement to New Mexico's existing submission. See CAA section 110(a)(1), (2) (requiring public notice and hearing requirements before SIP revisions may be submitted to EPA); *id.* CAA section 110(i) (prohibiting modifications of SIP requirements except as conducted pursuant to mandated SIP revision procedures); *id.* CAA section 110(l) (mandating analysis of all SIP revisions to ensure such revisions do not interfere with any applicable requirements under the Act). See also 40 CFR part 51, subpart F (setting forth minimum procedural requirements for the preparation, adoption, and submittal of implementation plans, including requirements of public notice and hearing); *id.* Appendix V, section 2 (setting forth administrative completeness criteria for State plan submissions including evidence of compliance with procedural requirements). However, the letter was provided to the EPA prior to this proposed document and the EPA has had time to consider its contents; the EPA in its discretion will provide its views on the relevance of the information contained in the letter.

In the letter, NMED explains that it believes the emissions reductions required under certain compliance orders in New Mexico applicable to several identified facilities will achieve greater emissions reductions than what would be achieved for New Mexico's EGU sources if those sources were subject to the Federal Good Neighbor Plan. NMED asserts that the EPA identified in the Federal Good Neighbor Plan that the control requirements for EGUs would achieve roughly 30 tons of ozone season NO_x emissions reductions on an annual basis through the strategies of SCR and SNCR optimization and upgrade of combustion control requirements at qualifying EGUs. In the letter, NMED identified 236 tons of already

established annual NO_x emissions reductions due to two compliance orders lodged in 2021 that it claims had not been reflected in the EPA's 2016v3 emissions platform, and an additional 77 tons of emissions reductions across 3 years from a consent decree with Matador Production Company.¹¹⁴ According to NMED, because these reductions are greater than the reductions that would be achieved under the Federal Good Neighbor Plan, there is no need to issue a FIP for New Mexico, since these other measures have already eliminated a greater mass-based quantity of emissions than the EPA found needed to eliminate significant contribution.

The Agency acknowledges and applauds the efforts to enforce air pollution control requirements and the reductions in ozone-precursor emissions that are claimed to be achieved under these orders. However, the information in this letter does not lead the EPA to a different conclusion with respect to the approvability of New Mexico's interstate transport SIP submission. In addition to the fact that the letter is not a formal SIP submission, the EPA does not believe the information contained in the letter (even if it were a SIP submission) is sufficient to allow the EPA to conclude that New Mexico would satisfy its obligations to eliminate significant contribution either at Step 2 or Step 3. The EPA welcomes the opportunity to further discuss with New Mexico the content of a future SIP revision that would satisfy these obligations.

Regarding the existence of a linkage at Step 2, although the letter asserts these reductions are additional to those reflected in the emissions inventories used in the 2016v3 modeling, this conclusion is not clearly supported. The emissions inventories used in the modeling reflected a specific methodology for calculating and projecting ozone-precursor emissions from the oil and gas sector in New Mexico and particularly in the Permian Basin. See Disapproval Action RTC at 117. The reductions that may be achieved at the particular facilities under compliance orders New Mexico cites do not necessarily establish that those emissions projections, including growth factors, used in the EPA's modeling for the oil and gas sector are unreliable. (In this regard, the EPA does not view the information in the letter as undercutting its determinations at Steps 1 and 2.)

Briefly, some additional concerns that the EPA has identified with the

approach suggested in New Mexico's letter include: (1) all new NO_x emissions reduction measures would need to be adopted into the SIP;¹¹⁵ (2) any assessment of emissions reductions would likely need to be in terms of the ozone season of May 1 through September 30 rather than annual reductions and would need to be established consistent with a relevant baseline date and compliance date;¹¹⁶ and (3) the approach would need to account for the impact of not placing additional NO_x limitations on EGU sources in determining the amount of NO_x emissions that New Mexico's SIP needs to reduce.

The Agency recognizes that states may replace a FIP with a SIP and the emissions controls in that SIP may differ from those the EPA selected in its FIP. See section VI.C. of this document. However, the mere existence of the compliance orders identified by NMED does not substitute for a Step 3 analysis and is insufficient in itself to support a conclusion that New Mexico has resolved its good neighbor obligations for the 2015 ozone NAAQS. Though there is not a single, prescribed method for how a State may conduct a Step 3 analysis, the EPA has consistently applied Step 3 of the good neighbor framework for ozone through a far more comprehensive evaluation of potential additional control technologies or measures, on industry-wide bases, than what New Mexico provided in its submission. Identifying various emissions control measures at specific units that have been enacted at the State level, is not analytically sufficient. And as explained above, the EPA has identified several additional concerns. First, as a *replacement* for the emissions control strategy that the Federal Good Neighbor Plan would implement at Step 4 in New Mexico, the letter is insufficient to demonstrate equivalence. Second, as noted above, these measures have not been included as a revision to New Mexico's SIP and submitted for EPA's approval.

f. Conclusion

The EPA is proposing to find that the portion of NMED's July 27, 2021 and EHD's June 9, 2021, SIP submission addressing Prong 2 of CAA section 110(a)(2)(D)(i)(I), interference with

¹¹⁵ The EPA made this requirement clear in its SIP Disapproval action. See 88 FR at 9343, 9376. In its letter, NMED has not indicated its intent to incorporate these orders and the commensurate NO_x emissions reductions into their SIP.

¹¹⁶ As such, the information in NMED's letter is inadequate to establish that these orders achieve an equivalent amount of emissions reduction to eliminate significant contribution as the Federal Good Neighbor Plan would in New Mexico.

¹¹⁴ NMED's July 5, 2023 letter, at 1.

maintenance of the 2015 ozone NAAQS, does not meet the State's interstate transport obligations, because it fails to contain the necessary provisions to prohibit emissions that will interfere with maintenance of the 2015 ozone NAAQS in any other state. Additionally, the EPA proposes to partially approve these submissions with respect to Prong 1 of the good neighbor provision regarding "significant contribution to nonattainment." The EPA in its discretion has considered the information in NMED's July 2023 letter but for the reasons explained in section IV.B.2.d. of this document, finds this information would not alter its conclusions as to New Mexico.

3. Tennessee

a. Evaluation of Information Provided by Tennessee Regarding Step 1

At Step 1 of the 4-step interstate transport framework, Tennessee relied on the EPA's 2011-based modeling included in the March 2018 memorandum to identify nonattainment and maintenance receptors in 2023. As described previously in section III.C. of this document, the EPA has updated this modeling (2016v3) using the most current and technically appropriate information and has used that information, along with its violating-monitor receptor identification methodology, to determine the final good neighbor obligations for 23 other states. To ensure parity among states, the EPA proposes to rely on this air quality analysis to identify nonattainment and maintenance receptors in the 2023 analytic year.

b. Evaluation of Information Provided by Tennessee Regarding Step 2

At Step 2 of the 4-step interstate transport framework, Tennessee relied on the 2011-based modeling released in

the March 2018 memorandum to identify upwind State linkages to nonattainment and maintenance receptors in 2023. As described in section III.C. of this document, the EPA has updated its air quality analytics (2016v3 modeling coupled with monitoring data to inform identification of violating-monitor receptors) to identify upwind State contributions to nonattainment and maintenance receptors in 2023. In this proposal, to ensure parity among states, the EPA relies on this set of analytics to identify upwind contributions ("linkages") to downwind air quality problems in the 2023 analytic year using a threshold of 1 percent of the NAAQS. *See* section III.D.3. of this document for explanation of the use of 1 percent of the NAAQS. This set of analytical data establishes that Tennessee is linked to violating-monitor receptors in 2023 in Dallas County, TX. as shown in Table IV.B.3–1, Tennessee's maximum contribution to a violating-monitor receptor is 0.86 ppb which is greater than 1 percent of the ozone standard (*i.e.*, 0.70 ppb). Therefore, Tennessee is linked to a downwind air quality problem at Steps 1 and 2. Because the entire technical basis for Tennessee's submission is that the State is not linked at Step 2, but the state-of-the-science analytics used to address all other states' obligations establishes that this is not correct, the EPA proposes to partially disapprove Tennessee's SIP submission based on the EPA's finding that Tennessee contributes above the threshold to at least one maintenance-only receptor in another state.¹¹⁷

The EPA's air quality analytics indicate that Tennessee is not linked to any model-projected nonattainment receptors above 1 percent of the NAAQS. As a result, no further evaluation of the State's emissions (*i.e.*, multifactor analysis, including air

quality and cost considerations emissions analysis) are required with respect to Prong 1 of section 110(a)(2)(D)(i)(I) of the CAA. This comports with the State's conclusions with regards to Prong 1, and therefore, the EPA proposes to partially approve Tennessee's SIP submission regarding Prong 1 of the good neighbor provision regarding "significant contribution to nonattainment."¹¹⁸

Tennessee references a 1 ppb threshold in its submission, citing the EPA's Significant Impact Level (SIL) Guidance as justification for the use of a 1 ppb threshold. The EPA explained in the final SIP Disapproval action that the SIL Guidance cannot be relied upon to justify an alternative threshold at Step 2 of the interstate transport framework for ozone. *See* 88 FR at 9372. The Agency is adopting that same position in relation to Tennessee's attempted reliance.

c. Results of EPA's Step 1 and Step 2 Modeling and Findings for Tennessee

As described in section III.B. of this document, the EPA performed updated air quality modeling (2016v3) to project design values and contributions for 2023. These data were examined to determine if Tennessee contributes at or above the threshold of 1 percent of the 2015 8-hour ozone NAAQS (0.70 ppb) to any downwind nonattainment or maintenance-only receptor. Based on the EPA's modeling results, Tennessee is not linked to a model-identified nonattainment or maintenance receptor in 2023 or 2026. However, as shown in Table IV.B.3–1, the data¹¹⁹ indicates that in 2023, emissions from Tennessee contribute greater than 1 percent of the standard to five violating-monitor maintenance-only receptors in the Dallas-Fort Worth-Arlington, Texas Core Based Statistical Area.^{120 121}

TABLE IV.B.3–1—TENNESSEE LINKAGE RESULTS BASED ON VIOLATING-MONITOR MAINTENANCE-ONLY RECEPTORS

Receptor ID	Location	2021 Design value (ppb)	2022 Design value (ppb)	2021 4th high (ppb)	2022 4th high (ppb)	Contribution (ppb)
481130075	Dallas County, TX	71	71	73	72	0.86
481211032	Denton County, TX	76	77	85	77	0.77
484392003	Tarrant County, TX	72	72	74	72	0.74
480850005	Collin County, TX	75	74	81	73	0.74
484390075	Tarrant County, TX	75	76	76	77	0.70

¹¹⁷ To the extent the Tennessee submittal included information regarding emissions controls that could be interpreted as relevant to a Step 3 analysis, the EPA evaluates that information in Section IV.C.3.d of this document.

¹¹⁸ Tennessee's largest impact on any modeled-projected downwind nonattainment and maintenance-only receptor are 0.60 ppb and 0.68

ppb, respectively. These values are less than 0.70 ppb (one percent of the 2015 ozone NAAQS).

¹¹⁹ Final Good Neighbor Plan AQM TSD, Appendix C, available in Docket ID No EPA–HQ–OAR–2021–0668.

¹²⁰ The EPA developed the violating-monitor approach in response to comments on the 2016v2 modeling received on the proposed Disapproval action and FIP. In this regard, EPA did not identify

violating-monitors in the contribution data associated with the 2016v1 and 2016v3 modeling.

¹²¹ As noted in section III.D.2. of this document, a violating-monitor receptor is not projected to have a maximum projected design value of 71 ppb or greater in 2023 based on the EPA's 2016v3 modeling results. Therefore, the receptors identified in Table IV.B.3–1 have both average and maximum projected design values below 70 ppb.

Therefore, based on the EPA's evaluation of the information in Tennessee's SIP submission considering the modeling results for 2023 and 2026 using the 2016v3 emissions platform and monitoring data used to inform the identification of violating-monitor receptors, the EPA proposes to find that Tennessee is not linked to a nonattainment receptor. However, the EPA finds that Tennessee is linked at Steps 1 and 2 to at least one maintenance-only receptor in another state.

d. Evaluation of Information Provided for Tennessee Regarding Step 3

To determine what, if any, emissions significantly contribute to nonattainment or interfere with maintenance and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I), at Step 3 of the 4-step interstate transport framework, a state's emissions are further evaluated, in light of multiple factors, including air quality and cost considerations. Tennessee did not conduct a Step 3 analysis in its SIP submission because at the time, the EPA's modeling indicated the State was not linked above 1 percent of the NAAQS to a projected downwind nonattainment or maintenance receptor. However, based on the EPA's updated air quality analytics, which the EPA has used to make final determinations for all other states, the State is currently linked to at least one downwind violating-monitor maintenance-only receptor. To ensure consistency and equity across all states in addressing good neighbor obligations for the 2015 ozone NAAQS, the EPA is evaluating the SIP submission in the context of this same set of air quality analytics. Tennessee's SIP submission does not analyze total ozone precursors that continue to be emitted from sources and other emissions activity within the State, evaluate the emissions reduction potential of any additional controls using cost or other metrics, nor evaluate any resulting downwind air quality improvements that could result from such controls. Instead, Tennessee's submission includes a list of existing emissions control programs and measures in the State. However, the EPA's modeling already takes account of such measures. Despite these existing emissions controls, the State is linked above 1 percent of the NAAQS to at least one downwind violating-monitor maintenance-only receptor.

Based on this record, the EPA finds the State's conclusion that its SIP contains adequate provisions prohibiting emissions interfering with maintenance of the 2015 ozone NAAQS

in other states to lack justification. Thus, the EPA proposes to partially disapprove Tennessee's SIP submission with respect to Prong 2 of CAA section 110(a)(2)(D)(i)(I), interference with maintenance of the 2015 ozone NAAQS.

e. Conclusion

The EPA proposes to partially disapprove the State's SIP submission with respect to Prong 2 regarding "interference with maintenance" of the good neighbor provision. Additionally, the EPA proposes to partially approve Tennessee's SIP submission with respect to Prong 1 of the good neighbor provision regarding "significant contribution to nonattainment."

C. Proposed SIP Action

The EPA is proposing to partially disapprove the portions of SIP submissions from Arizona, New Mexico, and Tennessee pertaining to interstate transport of air pollution that will interfere with maintenance of the 2015 8-hour ozone NAAQS in other states. Under CAA section 110(c)(1), disapproval would establish a 2-year deadline for the EPA to promulgate a FIP for Arizona, New Mexico, and Tennessee to address the CAA section 110(a)(2)(D)(i)(I) interstate transport requirements pertaining to interference with maintenance of the 2015 8-hour ozone NAAQS in other states, which the EPA proposes to do in this action, unless the EPA approves a SIP submission that meets these requirements. Disapproval of a good neighbor submission does not start a mandatory sanctions clock. Additionally, the EPA is proposing to partially approve the portions of SIP submissions from Arizona, New Mexico, and Tennessee pertaining to interstate transport of air pollution that will significantly contribute to nonattainment of the 2015 8-hour ozone NAAQS in other states.

As discussed in greater detail in sections VI. and VII. of this document, the EPA is proposing to determine based on application of the EPA's 4-step interstate transport framework, that there are emissions reductions that are required for Arizona, New Mexico, and Tennessee to satisfy their good neighbor obligations for the 2015 ozone NAAQS. The analysis on which the EPA proposes this conclusion for these three states is the same, nationally consistent analytical framework on which the Agency proposes FIP action for Kansas and Iowa in this proposed action (see section V.A. of this document), as well as for the 23 states included in its March 15, 2023, Federal Good Neighbor Plan.

V. Other Clean Air Act Authorities for this Action

A. Correction of the EPA's Determination Regarding SIP Submissions From Iowa and Kansas and Its Impact on the EPA's FIP Authority for Iowa and Kansas

In 2022, the EPA approved infrastructure SIP submissions from Iowa and Kansas for the 2015 ozone NAAQS, which in part addressed the good neighbor provision at CAA section 110(a)(2)(D)(i)(I).¹²² The EPA concluded that, based on the 2016v2 modeling, which was the latest modeling results available at the time the EPA took action, the largest impact on any potential downwind nonattainment or maintenance receptor from each of these states was less than 1 percent of the NAAQS.¹²³ As a result, the EPA found that neither Iowa nor Kansas would significantly contribute to nonattainment or interfere with maintenance in any other state.¹²⁴ Therefore, the EPA approved the portion of each State's infrastructure SIP submission that addressed CAA section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS.

Subsequent to the release of the 2016v2-based modeling and EPA's approval of Iowa's and Kansas' 2015 ozone NAAQS good neighbor SIP submission, the EPA performed updated modeling in response to comments received on other good neighbor proposals in 2022, as described in section III.C. of this document. Additionally, as described in section III.D.2. of this document, the EPA updated its definition of a maintenance receptor in recognition of comments and other information highlighting measured ozone levels continuing to exceed the 2015 ozone NAAQS at many monitoring sites throughout the country. The approach adopted in the Federal Good Neighbor Plan now takes into greater consideration monitoring data to determine whether a violating monitoring site will struggle to maintain

¹²² 87 FR 22463 (April 15, 2022) (Iowa); 87 FR 19390 (April 4, 2022) (Kansas).

¹²³ See "Air Quality Modeling Technical Support Document 2015 Ozone NAAQS Transport SIP Proposed Actions", available in Docket ID No. EPA-HQ-OAR-2021-0663.

¹²⁴ *Id.* at 17. Based on the 2023 modeling from the Proposed AQM TSD, Iowa was expected in 2023 to have a 0.64 ppb impact on a potential nonattainment receptor in Kenosha County, Wisconsin (Site ID 550590019) and a 0.58 ppb impact at a potential maintenance receptor in Cook County, Illinois (Site ID 170310032). Kansas was expected in 2023 to have a 0.49 ppb impact on a potential nonattainment receptor in Kenosha County, Wisconsin (Site ID 550590019) and a 0.060 ppb impact at a potential maintenance receptor in Cook County, Illinois (Site ID 170310001).

the NAAQS in the 2023 analytic year. The EPA used this new, unified set of air quality analytics to inform its determinations of the obligations of all other states. Iowa and Kansas have SIP approvals in place that are inconsistent with that common set of information used for other states, including those states that are linked to the same receptors to which Iowa and Kansas are now shown to be linked in 2023. As

such, the approvals were in error under CAA section 110(k)(6).

Based on this updated air quality modeling and considering contributions to violating-monitor receptors, both Iowa and Kansas are now projected to contribute more than 1 percent of the NAAQS to downwind receptors. Specifically, as shown in Table V.A–1, Iowa is projected to contribute 0.90 ppb to a maintenance-only receptor in Cook

County, Illinois (Site ID 170310001) and 0.70 ppb to a maintenance-only receptor in Kenosha, Wisconsin (Site ID 550590019) in the 2023 analytic year. As shown in Table V.A–2, Iowa is also linked to three violating-monitor receptors at locations in Illinois, Michigan, and Wisconsin, in the 2023 analytic year.

TABLE V.A–1—IOWA LINKAGE RESULTS BASED ON THE EPA UPDATED 2023 MODELING

Receptor ID	Location	Nonattainment/maintenance	2023 Average design value (ppb)	2023 Maximum design value (ppb)	Iowa contribution (ppb)
170310001	Cook, Illinois	Maintenance-Only	68.2	71.9	0.90
550590019	Kenosha, Wisconsin	Maintenance-Only	70.8	71.7	0.70

Source: Final Good Neighbor Plan AQM TSD

TABLE V.A–2—IOWA 2023 LINKAGE RESULTS BASED ON VIOLATING-MONITOR MAINTENANCE-ONLY RECEPTORS

Receptor ID	Location	2021 Design value (ppb)	2022 Design value (ppb)	2021 4th high (ppb)	2022 4th high (ppb)	Iowa contribution (ppb)
260050003	Allegan, Michigan	75	75	78	73	1.13
170310032	Cook, Illinois	75	75	77	72	0.79
550590025	Kenosha, Wisconsin	72	73	72	71	0.71

Source: Final Good Neighbor Plan AQM TSD.

Table V.A–3 shows that Kansas is projected to contribute 0.82 ppb to the violating-monitor receptor in Allegan,

MI (Site ID 260050003) in the 2023 analytic year.

TABLE V.A–3—KANSAS 2023 LINKAGE RESULTS BASED ON VIOLATING-MONITOR MAINTENANCE-ONLY RECEPTORS

Receptor ID	Location	2021 Design value (ppb)	2022 Design value (ppb)	2021 4th high (ppb)	2022 4th high (ppb)	Kansas contribution (ppb)
260050003	Allegan, Michigan	75	75	78	73	0.82

Source: Final Good Neighbor Plan AQM TSD.

Iowa and Kansas are not projected to be linked above 1 percent of the NAAQS to receptors in the 2026 analytic year. The reasons for the changes in linkages in the 2016v3 modeling for Iowa are driven by a combination of factors. The EPA explained in the Federal Good Neighbor Plan that the 2016v3 modeling contains several changes to improve its performance from the 2016v2 modeling, particularly in recognition of an apparent under-prediction problem particularly in the Upper Midwest. 88 FR at 36697; *see also* 88 FR at 9344–45. The EPA made changes to better incorporate the effects of biogenic emissions sources, lightning, and international/boundary conditions on ozone levels, and observed an improvement from a 19 percent underprediction to a 6.9 percent under prediction in the Upper Midwest. *Id.*

The EPA also updated its anthropogenic-source emissions inventory data for all states, including Iowa and Kansas. *Id.* At 36698. The change in linkages for Kansas is attributable to the development of the violating-monitor receptor methodology for identifying additional maintenance-only receptors, coupled with updated calculations of contribution levels derived from the updated 2016v3 modeling.

The same air quality monitoring data and modeling used to analyze the analytic years 2023 and 2026 has been used in taking final action to define the obligations of 23 states already covered in the Federal Good Neighbor Plan. As explained in section I.A. of this document, the Agency finds it both reasonable—and necessary to ensuring consistency and equity across all

states—to use this same analytical information to address the obligations of all states. These data are state-of-the-science regarding air quality conditions and contribution levels in 2023 and 2026, reflecting improvements in the EPA's understanding from the 2016v2 modeling and incorporating the input of many outside parties through their public comments during the rulemaking process. Using these data, methodological choices, and analytical findings, the EPA has determined that Kansas and Iowa each contribute to at least one maintenance receptor greater than 1 percent of the 2015 ozone NAAQS. Therefore, the EPA is proposing to find that its approval of each State's 2015 ozone NAAQS infrastructure SIP submission, with regard only to the portion addressing Prong 2 of the good neighbor provision

at CAA section 110(a)(2)(D)(i)(I), was in error.

Section 110(k)(6) of the CAA gives the Administrator authority, without any further submission from a state, to revise certain prior actions, including actions to approve SIP submissions, upon determining that those actions were in error.¹²⁵ The EPA's state-of-the-science analysis used in the Federal Good Neighbor Plan demonstrates that the EPA's prior conclusions that Iowa and Kansas will not interfere with maintenance in any other State in the 2023 analytic year was incorrect, which means that the EPA's approvals of Iowa's and Kansas' good neighbor SIP submissions were in error.

The Agency's use of error-correction authority in this instance is well-rooted in the statute and case law and is consistent with the EPA's longstanding practice and policy of addressing states' good neighbor obligations using state-of-the-science air quality analysis in a consistent manner across all states.

Section 110(k)(6) of the CAA provides the EPA with the authority to make corrections to actions on CAA implementation plans that are subsequently found to be in error. *Ass'n of Irrigated Residents v. EPA*, 790 F.3d 934, 948 (9th Cir. 2015) (110(k)(6) is a "broad provision" enacted to provide the EPA with an avenue to correct errors). The key provisions of CAA section 110(k)(6) are that the Administrator has the authority to "determine" that the approval or promulgation of a plan was "in error," and when the Administrator so determines, he may then revise the action "as appropriate," in the same manner as the prior action.¹²⁶ Moreover, CAA section 110(k)(6) "confers discretion on the EPA to decide if and when it will invoke the statute to revise a prior action." 790 F.3d at 948 (CAA section 110(k)(6) grants the "EPA the discretion to decide when to act pursuant to that provision"). While CAA section 110(k)(6) provides the EPA with the authority to correct its own "error," nowhere does this provision or any other provision in the CAA define what qualifies as "error." Thus, the EPA concludes that the term should be given its plain language, everyday meaning, which includes all unintentional, incorrect, or wrong actions or

mistakes.¹²⁷ Under CAA section 110(k)(6), the EPA must make an error determination and provide "the basis thereof." There is no indication that this is a substantial burden for the Agency to meet. To the contrary, the requirement is met if the EPA clearly articulates the error and its basis. *Ass'n of Irrigated Residents v. EPA*, 790 F.3d at 948; *see also* 85 FR 73636, 73638.

In this action, the EPA proposes to determine that it made an error in approving Kansas' and Iowa's good neighbor SIP submittals. The EPA based its prior approvals on the conclusion that these states would not contribute above 1 percent of the NAAQS to any receptors in 2023, using modeling information that has since been updated to incorporate public comment and better information, is no longer considered state-of-the-science, and produces a different result for these states, one which is inconsistent with the set of air quality analysis used to inform the EPA's evaluation of all other states. *See* 88 FR 9344–45, 9349–50 (explaining updates to improve model performance and account for recent monitored ozone levels in response to public comments). Had the EPA known of this information regarding the 2023 analytic year reflected in the 2016v3 modeling and the violating-monitor receptor identification methodology at the time it issued those approvals, it would not have approved Kansas or Iowa's submissions. Under the plain meaning of the word "error," those approvals were in error and are in need of correction.

Application of the final air quality analysis and contribution information from the Federal Good Neighbor Plan in this manner is consistent with longstanding EPA practice and policy under the good neighbor provision. The EPA explained in the Disapproval action its view that use of updated information to inform its action on the states included in the Disapproval action was not prejudicial, in part because, had the Agency approved any of those states based on modeling that had been superseded by more recent and reliable information, it would exercise error correction authority under CAA section 110(k)(6) as it had done in the past, to convert those approvals to disapprovals (as it is now doing here). *See* 88 FR at 9364. The EPA explained that this would be consistent with prior error-correction actions it has taken or proposed under the good neighbor provision. *See id.* (citing 86 FR 23056, 23067–68 (April 30, 2021) (error correcting Kentucky's approval to a

disapproval and promulgating FIP addressing Kentucky's outstanding 2008 ozone NAAQS good neighbor obligations); 87 FR 20036, 20041 (April 6, 2022) (proposing error correction for Delaware's 2015 ozone NAAQS SIP approval to a disapproval based on updated air quality modeling)). Similarly, in the original CSAPR rulemaking, the EPA issued error corrections under CAA section 110(k)(6) authority for 22 states where the EPA had issued approvals of SIPs adopted under the Clean Air Interstate Rule (CAIR), following the D.C. Circuit's decision in *North Carolina* that CAIR's "emissions budgets were insufficiently related to the statutory mandate" of the good neighbor provision. *See* 76 FR 48208, 48220–22 (Aug. 8, 2011). The D.C. Circuit upheld this exercise of error-correction authority in *EME Homer City*, 795 F.3d 118, 132–35 (D.C. Cir. 2015).

The 22 error corrections in the original CSAPR and for Kentucky in the Revised CSAPR Update were prompted by judicial decisions that invalidated the reasoning that the EPA had used to support the approvals. In those circumstances, a change in the law occurring subsequent to the time of the EPA's original action on the SIPs, and which the EPA could not have been aware of at the time that it took such action, justified the use of error-correction authority. Likewise, a change in the EPA's understanding of the relevant facts, even if that understanding could not have been known at the time of the EPA's original action, may equally justify the exercise of error-correction authority.¹²⁸ The EPA does not read the statute to only authorize the use of error correction authority under 110(k)(6) when a judicial decision or other change in legal view or interpretation has been brought to light. This would read into the statute a term that is not there, namely, that the EPA can only exercise CAA section 110(k)(6) authority when there is a "legal" error. As explained previously, the statute does not say this. It only uses the term "error"; that term is not defined, and its plain meaning encompasses errors of law or fact. In this case, while no intervening judicial decision or change in legal

¹²⁵ *See, e.g.*, 86 FR 23054, 23068 (error correcting prior approval of Kentucky's transport SIP submission for the 2008 ozone NAAQS to a disapproval and simultaneously promulgating FIP on the basis of the *Wisconsin* and *New York* decisions remanding CSAPR Update and vacating CSAPR Close-Out and new information establishing Kentucky was linked to downwind receptors).

¹²⁶ *See* 85 FR 73636, 73637 (November 19, 2020).

¹²⁷ *See* 85 FR at 73637–38.

¹²⁸ The court in *EME Homer City* noted that its holding was limited to the circumstance where "a federal court says that EPA lacked statutory authority at the time to approve a SIP." 795 F.3d at 135 n.12. However, this statement was in relation to its holding that the EPA had properly invoked the good cause exception of the Administrative Procedure Act to issue those error corrections without public notice and comment. *See id.* The EPA does not read this statement as a limitation on the exercise of error-correction authority generally.

interpretation has prompted this proposed error correction, this is no way diminishes the appropriate exercise of CAA section 110(k)(6) error correction authority in this instance. The EPA approved Kansas's and Iowa's SIPs based on a mistaken belief that they would not contribute above the 1 percent threshold to receptors in 2023. The updated air quality and contribution analysis that the EPA used to render final determinations in the Disapproval action and Federal Good Neighbor Plan as to all other states' interstate transport obligations for the 2015 ozone NAAQS now indicates these findings were in error. To align the treatment of these states with all others, it is not only reasonable, but necessary for consistency and equity, to correct these approvals to disapprovals. To clarify, if Kansas and Iowa are not required to now meet their interstate transport obligations based on this new information, other upwind states as well as the downwind areas to which they are linked could bear a greater burden to reduce air pollution.

In making this proposed determination, the EPA observes that all other states whose good neighbor SIP submissions had previously been approved using older data are found in the 2023 and 2026 air quality analysis used in the Federal Good Neighbor Plan to continue not to contribute above 1 percent of the NAAQS at any receptors. Thus, there remains no need to revisit those approvals, because the updated air quality analysis does not indicate that they were in error. Similarly, where the EPA's final analysis in the Federal Good Neighbor Plan indicated that, contrary to prior expectations, a State is *not* linked above 1 percent of the NAAQS to any receptors, the EPA has taken action to approve that State's submission. This is the case for Wyoming. *See* 88 FR 54998 (Aug. 14, 2023). In no case has the EPA issued a final *disapproval* of a good neighbor SIP submittal for the 2015 ozone NAAQS, only to find that State *not* linked in the 2016v3 modeling or pursuant to its violating-monitor receptor identification methodology. Had this circumstance arisen, consistent with the position adopted here, the EPA fully expects it would have acted under CAA section 110(k)(6) to correct such a disapproval to an approval.¹²⁹

Finally, the EPA affirms in general that it does not view all modeling

results as subject to obligatory (or even discretionary) revision under error-correction authority, simply because later information shows a modeling projection to deviate from subsequent modeling or real-world information. Agencies such as the EPA, regulating in a scientifically complex arena such as the CAA, must be able to make and rely on modeling projections, and this reliance is appropriate and lawful even if modeling projections later may be found to deviate from real-world information. *See EME Homer City*, 795 F.3d at 135 ("We will not invalidate EPA's predictions solely because there might be discrepancies between those predictions and the real world."); *see also Wisconsin*, 938 F.3d at 318 (holding that the EPA must implement the Act even in the face of uncertainty). However, the distinction here is in the fact that, following the approval of Kansas' and Iowa's SIPs, new modeling information (and other air quality analysis) was developed that informed, on a nationally consistent basis, the EPA's determinations regarding the good neighbor obligations of all other states. The EPA finds that in this circumstance, error correction under CAA section 110(k)(6) is warranted and appropriate.

In proposing these error corrections, the Agency has reviewed the original submittals from Iowa and Kansas. The Agency finds no information, analysis, or implementation of control measures in these submittals that could warrant approval on an alternative basis. The EPA finds that neither Kansas nor Iowa submitted an appropriate analysis of receptor specific information that could justify the application of a higher Step 2 screening threshold of 1 ppb. As explained in section III.D.3. of this document, the Agency has concluded that it will not conduct such an analysis for any states that failed to develop such an analysis themselves, and further, the Agency has explained through both its Disapproval action and Federal Good Neighbor Plan rulemakings that it would not be wise policy and would frustrate the goals of consistency and equity among states in addressing interstate ozone pollution, to attempt to recognize alternative contribution thresholds in various states. 88 FR at 9371–75. In addition, neither Kansas or Iowa submitted an analysis of emissions control strategies or alternative frameworks for analysis at Step 3 that could justify approval of their submissions on that basis. Further, neither State provided any enforceable emissions control measures in their submissions.

Therefore, the EPA proposes to correct its error in approving Iowa's and Kansas' good neighbor SIP submissions. This error correction under CAA section 110(k)(6) would revise the approval of the portion of Iowa's and Kansas' 2015 ozone NAAQS infrastructure SIP submission that addresses CAA section 110(a)(2)(D)(i)(I) to a partial disapproval as to Prong 2 and rescinds any statements that the portion of Iowa's and Kansas' infrastructure SIP submission that addresses CAA section 110(a)(2)(D)(i)(I), Prong 2, satisfies the requirements of the good neighbor provision. The EPA's approval of these SIP submissions as to Prong 1 of the good neighbor provision is not proposed to be changed. The EPA is not proposing to correct the elements of Iowa's and Kansas' 2015 ozone NAAQS infrastructure SIP submission that do not address CAA section 110(a)(2)(D)(i)(I).

Under CAA section 110(c)(1), finalization of this partial disapproval would establish a 2-year deadline for the EPA to promulgate a FIP for Kansas and Iowa to address the CAA section 110(a)(2)(D)(i)(I) interstate transport requirements pertaining to significant contribution to nonattainment and interference with maintenance of the 2015 8-hour ozone NAAQS in other states, which the EPA proposes to do in this action, unless the EPA approves a SIP submission that meets these requirements. Disapproval of a good neighbor submission does not start a mandatory sanctions clock.

As discussed in greater detail in sections VI. and VII. of this document, the EPA is proposing to determine based on application of the EPA's 4-step interstate transport framework, that there are emissions reductions that are required for Iowa and Kansas to satisfy their good neighbor obligations for the 2015 ozone NAAQS. The analysis on which the EPA proposes this conclusion for Iowa and Kansas is the same, nationally consistent analytical framework on which the Agency proposes FIP action for the other states in this proposed action, as well as for the 23 states included in its March 15, 2023, Federal Good Neighbor Plan.

B. Application of Rule in Indian Country and Necessary or Appropriate Finding

In the Federal Good Neighbor Plan, the EPA finalized its determination that the rule is applicable in all areas of Indian country (as defined at 18 U.S.C. 1151) within the covered 23-state geography of the final rule, as explained

¹²⁹ For the same reasons, this is not a circumstance in which the error correction is based in any sense on a change in agency policy. The use of error correction authority in this case is in keeping with the EPA's previously stated policy and consistent with its practices in evaluating good neighbor obligations. *See* 88 FR 9364.

in section III.C.2. of that action.¹³⁰ Here in this action, the EPA proposes to apply this determination to all areas of Indian country within the covered geography of this proposed rule. Certain areas of Indian country within the geography of the rule are or may be subject to State implementation planning authority. For the other areas of Indian country within that geography, none of the relevant tribes has as yet sought eligibility to administer a Tribal plan to implement the good neighbor provision.¹³¹ Consistent with its final determination in section III.C.2. of the Federal Good Neighbor Plan, the EPA is proposing to include all areas of Indian country within the covered geography of this rule, notwithstanding whether those areas are currently subject to a State's implementation planning authority.

With respect to areas of Indian country not currently subject to a State's implementation planning authority—*i.e.*, Indian reservation lands and other areas of Indian country over which the EPA or a tribe has demonstrated that a tribe has jurisdiction—the EPA here proposes a “necessary or appropriate” finding that direct Federal implementation of the rule's requirements is warranted under CAA section 301(d)(4) and 40 CFR 49.11(a) (the areas of Indian country subject to this finding are referred to later as the CAA section 301(d) FIP areas). Indian Tribes may, but are not required to, submit Tribal plans to implement CAA requirements, including the good neighbor provision. Section 301(d) of the CAA and 40 CFR part 49 authorize the Administrator to treat an Indian Tribe in the same manner as a State (*i.e.*, Treatment As State (TAS)) for purposes of developing and implementing a Tribal plan that addresses good neighbor obligations. *See* 40 CFR 49.3; *see also* “Indian Tribes: Air Quality Planning and Management,” hereafter “Tribal Authority Rule” (63 FR 7254, February 12, 1998). The EPA is authorized to directly implement the good neighbor provision in the 301(d) FIP areas when it finds, consistent with the authority of CAA section 301—which the EPA has exercised in 40 CFR 49.11—that it is necessary or appropriate to do so.¹³²

The EPA proposes in this action to find that it is both necessary and appropriate to regulate all new and existing EGU and non-EGU sources meeting the applicability criteria set forth in this proposed rule in the 301(d) FIP areas that are located within the geographic scope of coverage of the rule. For purposes of this proposed finding, the geographic scope of coverage of the rule means the areas of the United States encompassed within the borders of the states of Arizona, Iowa, Kansas, New Mexico, and Tennessee.¹³³ For EGU applicability criteria, *see* section VII.A. of this document; for non-EGU applicability criteria, *see* section VII.B. of this document. To the EPA's knowledge, there are two existing EGU sources located within the 301(d) FIP areas: the South Point Energy Center located on the Fort Mojave Reservation, and the Four Corners Power Plant on the Navajo Reservation. These EGU sources are geographically located within the borders of Arizona and New Mexico, respectively.¹³⁴

This proposed finding is consistent with the EPA's prior good neighbor rules, including the Federal Good Neighbor Plan. In prior rulemakings under the good neighbor provision, the EPA has included all areas of Indian country within the geographic scope of those FIPs, such that any new or existing sources meeting the rules' applicability criteria would be subject to the rule. In the CSAPR, the CSAPR Update, and the Revised CSAPR Update, the scope of the emissions trading programs established for EGUs extended to cover all areas of Indian country located within the geographic boundaries of the covered states. In these rules, at the time of their promulgation, no existing units were located in the covered areas of Indian country; under the general applicability criteria of the trading programs, however, any new sources located in such areas would become subject to the

appropriate to protect air quality and requires the EPA to promulgate such rulemaking”); *Safe Air For Everyone v. U.S. Env't Prot. Agency*, No. 05–73383, 2006 WL 3697684, at *1 (9th Cir., Dec. 15, 2006) (“The statutes and regulations that enable EPA to regulate air quality on Indian reservations provide EPA with broad discretion in setting the content of such regulations.”).

¹³³ With respect to any non-EGU sources located in the 301(d) FIP areas, the geographic scope of coverage of this proposed rule does not include those states for which the EPA proposes to find, based on air quality modeling, that no further linkage exists by the 2026 analytic year at Steps 1 and 2. The only State in this rule projected to be linked in 2026 is Arizona.

¹³⁴ The EPA is currently not aware of any existing non-EGU sources that are located within the 301(d) FIP areas within Arizona's borders that meet the non-EGU applicability criteria.

programs. Thus, the EPA established a separate allowance allocation that would be available for any new units locating in any of the relevant areas of Indian country. *See, e.g.*, 76 FR at 48293 (describing the CSAPR methodology of allowance allocation under the “Indian country new unit set-aside” provisions); *see also id.* at 48217 (explaining the EPA's source of authority for directly regulating in relevant areas of Indian country as necessary or appropriate). Further, in any action in which the EPA subsequently approved a State's SIP submission to partially or wholly replace the provisions of a CSAPR FIP, the EPA has clearly delineated that it will continue to administer the Indian country new unit set aside for sources in any areas of Indian country geographically located within a State's borders and not subject to that State's CAA planning authority, and the State may not exercise jurisdiction over any such sources. *See, e.g.*, 82 FR 46674, 46677 (October 6, 2017) (approving Alabama's SIP submission establishing a State CSAPR trading program for ozone season NO_x, but providing, “The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.”).

For this proposed rulemaking, the EPA proposes to take the same approach with respect to regulating sources in the 301(d) FIP areas as was finalized in the Federal Good Neighbor Plan. The EPA finds this approach is necessary and appropriate for several reasons. First, as an extension of the Federal Good Neighbor Plan, the purpose of this rule is to address the interstate transport of ozone on a national scale. Consistent with its findings regarding the broad upwind region covered by the Federal Good Neighbor Plan, the EPA proposes to extend into the geography of these five additional states a uniform level of emissions-control stringency. (*See* section VI. of this document for a discussion of the EPA's determination of control stringency for this proposal.) Within this approach, consistency in rule requirements across all jurisdictions is vital in ensuring the remedy for ozone transport is, in the words of the Supreme Court, “efficient and equitable,” 572 U.S. 489, 519. In particular, as the Supreme Court found in *EME Homer City Generation*, allocating responsibility through uniform levels of control across the entire upwind geography is “equitable” because, by imposing uniform cost thresholds on regulated States, the EPA's rule subjects to stricter regulation

¹³⁰ 88 FR at 36690–93.

¹³¹ Under 40 CFR 49.4(a), tribes are not subject to the specific plan submittal and implementation deadlines for NAAQS-related requirements, including deadlines for submittal of plans addressing transport impacts.

¹³² *See Arizona Pub. Serv. Co. v. U.S. E.P.A.*, 562 F.3d 1116, 1125 (10th Cir. 2009) (stating that 40 CFR 49.11(a) “provides the EPA discretion to determine what rulemaking is necessary or

those States that have done relatively less in the past to control their pollution. Upwind States that have not yet implemented pollution controls of the same stringency as their neighbors will be stopped from free riding on their neighbors' efforts to reduce pollution. They will have to bring down their emissions by installing devices of the kind in which neighboring States have already invested. *Id.*

In the context of addressing regional-scale ozone transport in this proposal, a uniform level of stringency that extends to and includes the 301(d) FIP areas geographically located within the boundaries of the linked upwind states carries significant force. Failure to include all such areas within the scope of the rule creates a significant risk that these areas may be targeted for the siting of facilities emitting ozone-precursor pollutants to avoid the regulatory costs that would be imposed under this proposed rule in the surrounding areas of State jurisdiction. Electricity generation or the production of other goods and commodities may become more cost-competitive at any EGUs or non-EGUs not subject to the rule but located in a geography where all surrounding facilities in the same industrial category are subject to the rule. For instance, the affected EGU sources located on the Fort Mojave Reservation of the Fort Mojave Indian Tribe and the Navajo Reservation of the Navajo Nation are both in areas covered by the interconnected western electricity grid. The EGU source on the Fort Mojave Reservation is owned by a large merchant power supplier and the EGU source on the Navajo Reservation is jointly owned by entities that supply electricity to customers in several states. It is both necessary and appropriate, in the EPA's view, to avoid creating, via this proposed rule, a structure of incentives that may cause generation or production—and the associated NO_x emissions—to shift into the 301(d) FIP areas to escape regulation needed to eliminate interstate transport under the good neighbor provision.

The EPA finds it is appropriate to propose direct Federal implementation of the proposed rule's requirements in the 301(d) FIP areas at this time rather than at a later date. Tribes generally have the opportunity to seek TAS and to undertake Tribal implementation plans under the CAA. To date, no tribe relevant to an existing EGU in the 301(d) FIP areas for the 2015 ozone NAAQS (or for any other NAAQS) has expressed an intent to do so for purposes of regulating interstate transport of air pollution under CAA section 110(a)(2)(D). Nor has the EPA

heard such intentions from any other tribe within the geography of this rule, and it would not be reasonable to expect tribes to undertake that planning effort, particularly when no existing sources are currently located on their lands. Further, the EPA is mindful that under court precedent, the EPA and states generally bear an obligation to fully implement any required emissions reductions to eliminate significant contribution under the good neighbor provision as expeditiously as practicable and in alignment with downwind areas' attainment schedule under the Act. As discussed in section VII.A. of this document, the EPA anticipates implementing certain required emissions reductions by the 2025 ozone season, and, for Arizona, additional required emissions reductions by the 2027 ozone season. Absent this proposed Federal implementation plan in the 301(d) FIP areas, NO_x emissions from any existing or new EGU or non-EGU sources located in, or locating in, the 301(d) FIP areas within the covered geography of the rule would remain unregulated and could potentially increase. This would be inconsistent with the EPA's overall goal of aligning good neighbor obligations with the downwind areas' attainment schedule and to achieve emissions reductions as expeditiously as practicable.

Further, the EPA recognizes that Indian country, including the 301(d) FIP areas, is often home to communities with environmental justice concerns, and these communities may bear a disproportionate level of pollution burden as compared with other areas of the United States. The EPA's draft Strategic Plan for Fiscal Year 2022–2026¹³⁵ includes an objective to promote environmental justice at the Federal, Tribal, state, and local levels and states: "Integration of environmental justice principles into all EPA activities with Tribal governments and in Indian country is designed to be flexible enough to accommodate EPA's Tribal program activities and goals, while at the same time meeting the Agency's environmental justice goals." By including all areas of Indian country within the covered geography of the rule, the EPA is advancing environmental justice, lowering pollution burdens in such areas, and preventing the potential for "pollution havens" to form in such areas as a result of facilities seeking to locate there to avoid the requirements that would

otherwise apply outside of such areas under this proposed rule.

Therefore, to ensure timely alignment of all needed emissions reductions with the larger timetable of this proposed rule, to ensure equitable distribution of the upwind pollution reduction obligation across all upwind jurisdictions, to avoid perverse economic incentives to locate sources of ozone-precursor pollution in the 301(d) FIP areas, and to deliver greater environmental justice, including protection for Tribal communities in line with Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All,¹³⁶ the EPA proposes to find it both necessary and appropriate that all existing and new EGU and non-EGU sources that are located in the 301(d) FIP areas within the geographic boundaries of the covered states, and which would be subject to this rule if located within areas subject to State CAA planning authority, should be included in this rule. The EPA proposes this finding under section 301(d)(4) of the Act and 40 CFR 49.11. Further, to avoid "unreasonable delay" in promulgating this FIP, as required under § 49.11, the EPA concludes it is appropriate to make this proposed finding now, to align emissions reduction obligations for any covered new or existing sources in the section 301(d) FIP areas with the larger schedule of reductions under this proposed rule. Because all other covered EGU and non-EGU sources within the geography of this proposed rule would be subject to emissions reductions of uniform stringency beginning in the 2025 ozone season, and as necessary to fully and expeditiously address good neighbor obligations for the 2015 ozone NAAQS, there is little benefit to be had by not proposing to include the 301(d) FIP areas in this rule now and a potentially significant downside to not doing so.

The EPA will continue to consult with the governments of the Fort Mojave Indian Tribe of the Fort Mojave Reservation, the Navajo Nation of the Navajo Reservation, and any other tribe wishing to continue consultation, during the comment period for this proposal. The EPA invites comment on this proposed finding.

¹³⁵ <https://www.epa.gov/system/files/documents/2021-10/fy-2022-2026-epa-draft-strategic-plan.pdf>.

¹³⁶ Executive Order 14096 (April 21, 2023): <https://www.federalregister.gov/documents/2023/04/26/2023-08955/revitalizing-our-nations-commitment-to-environmental-justice-for-all>.

VI. Quantifying Upwind-State NO_x Emissions Reduction Potential To Reduce Interstate Ozone Transport for the 2015 Ozone NAAQS

A. Summary of Multi-Factor Test

This section describes the EPA's methodology at Step 3 of the 4-step interstate transport framework for identifying upwind emissions that constitute "significant" contribution or interference with maintenance for the five states identified in the previous sections. The EPA proposes to apply the same analysis to these states that it applied for 23 states in the Federal Good Neighbor Plan.¹³⁷ To summarize this analysis: The EPA applies a multi-factor test at Step 3. The multi-factor test considers cost, available emissions reductions, downwind air quality impacts, and other factors (e.g., controls that have been widely adopted by like sources in other upwind states and/or in downwind areas with ozone attainment problems) to determine the appropriate level of control stringency that would eliminate significant contribution to downwind nonattainment or maintenance receptors. The selection of a uniform level of NO_x emissions control stringency across all of the linked states, reflected by representative cost per ton of emissions reduction figures for EGUs and the identified units in non-EGU industries, were principal findings from the final Federal Good Neighbor Plan. These findings serve to apportion the reduction responsibility among collectively contributing upwind states. The EPA proposes to apply these same findings to five additional states. As explained in section I.A. of this document, these states are being addressed in this separate rulemaking due to a happenstance resulting from rulemaking procedures and the timing of development of information that informed action on other states. As such, these states are not substantively situated differently in a meaningful or material way from any of the other states for which the EPA has already rendered a final determination of the appropriate level of emissions-control stringency to eliminate significant contribution for the 2015 ozone NAAQS. Had the EPA originally included these five states in its multifactor test considering emissions reduction potential across all linked states for this 2015 ozone NAAQS, the Agency would have made the same control stringency determination due to the comparable air quality circumstances and cost-effective emissions reduction opportunities

across the linked upwind-state geography.

The EPA therefore proposes to extend these findings on a uniform basis to these five additional states. This approach to quantifying upwind State emission-reduction obligations using a uniform level of control stringency was reviewed by the Supreme Court in *EME Homer City Generation*, which held that using such an approach to apportion emissions reduction responsibilities among upwind states that are collectively responsible for downwind air quality impacts "is an efficient and equitable solution to the allocation problem the good neighbor provision requires the Agency to address." 572 U.S. at 519.

In the final Federal Good Neighbor Plan, the EPA's analysis focused on NO_x as the primary ozone-precursor pollutant of concern.¹³⁸ The EPA then conducted four analytical steps as part of the Step 3 multifactor test to arrive at an appropriate level of stringency that eliminated significant contribution and/or interference with maintenance. These were: (1) identify levels of uniform NO_x control stringency; (2) evaluate potential NO_x emissions reductions associated with each identified level of uniform control stringency; (3) assess air quality improvements at downwind receptors for each level of uniform control stringency; and (4) select a level of control stringency considering the identified cost, available NO_x emissions reductions, and downwind air quality impacts, while also ensuring that emissions reductions do not unnecessarily over-control upwind-state emissions relative to the contribution threshold applied at Step 2 or the resolution of downwind receptors at Step 1. The remainder of this section summarizes the application of this analytical framework to the EGU and

non-EGU sources in Arizona, Iowa, Kansas, New Mexico, and Tennessee.

For both EGUs and non-EGUs, section VI.B. of this document describes the available NO_x emissions controls that the EPA evaluated for this proposed rule and their representative cost levels (in 2016\$). Section VI.C. of this document discusses the EPA's application of that information to assess emissions reduction potential of the identified control stringencies. Finally, section VI.D. of this document describes the EPA's assessment of associated air quality impacts and proposed determination of significant contribution. Section VI.D. of this document also describes the analysis the Agency conducted to evaluate if its selected control strategy would result in over-control for any upwind state, that is, whether an upwind State could have reduced its air quality contributions below the 1 percent of NAAQS air quality contribution threshold at a lower level of emissions-control stringency than identified in the GNP.

As in the Federal Good Neighbor Plan, the EPA applies its multi-factor test at Step 3 to EGUs and non-EGUs on consistent but parallel tracks. Following the conclusions of the EGU and non-EGU multi-factor tests, the identified reductions for EGUs and non-EGUs are combined and collectively analyzed to assess their effects on downwind air quality and whether the proposed rule achieves a full remedy to eliminate "significant contribution" while avoiding over-control.

As described in section III.D.4. of this document and described in this section, the EPA proposes that it is reasonable and equitable to apply the same nationally-determined level of uniform emissions-control stringency already determined in the final Federal Good Neighbor Plan for 23 states to these five additional states. The EPA is aware of no state-specific circumstances as to any of these five states that would warrant different treatment or analysis than has already been applied on a nationwide basis in the Federal Good Neighbor Plan.

B. Summary of Control Stringency Levels

1. EGUs

The Federal Good Neighbor Plan analyzed five NO_x emissions control strategies at EGUs: (1) fully operating existing SCR, including both optimizing NO_x removal by existing operational SCRs and turning on and optimizing existing idled SCRs; (2) installing state-of-the-art NO_x combustion controls; (3) fully operating existing SNCRs,

¹³⁸ As described in the Federal Good Neighbor Plan (88 FR 36719) the EPA examined the results of the contribution modeling performed for that rule to identify the portion of the ozone contribution attributable to anthropogenic NO_x emissions versus VOC emissions from each linked upwind State to each downwind receptor. From that analysis, the Agency concluded that the vast majority of the downwind air quality areas addressed by the Federal Good Neighbor Plan are primarily NO_x-limited, rather than VOC-limited. Therefore, the EPA found that regulation of NO_x emissions was necessary while regulation of VOCs as an ozone precursor in upwind states was not necessary to eliminate significant contribution or interference with maintenance in downwind areas in that rule. Considering that many of the downwind locations are the same in this rulemaking, and that the EPA is relying on the same air quality modeling, the EPA affirms that the conclusions about regulation of NO_x emissions relative to VOCs from the final Federal Good Neighbor Plan apply in this rulemaking.

¹³⁷ See 88 FR at 36718.

including both optimizing NO_x removal by existing operational SNCRs and turning on and optimizing existing idled SNCRs; (4) installing new SNCRs; and (5) installing new SCR.

In prior good neighbor rules, the EPA typically evaluated the potential for emissions reductions from generation shifting at the representative cost for each mitigation technology. This is because shifting generation to lower NO_x emitting or zero-emitting EGUs may occur in response to economic factors. As the cost of emitting NO_x increases, it becomes increasingly cost-effective for units with lower NO_x rates to increase generation, while units with higher NO_x rates reduce generation. Because the cost of generation is unit-specific, this generation shifting occurs incrementally on a continuum.

However, for reasons described in the preamble for the Federal Good Neighbor Plan, the EPA determined that it was not appropriate to incorporate emissions reductions from generation shifting.¹³⁹

For the same reasons, the EPA does not quantify emissions reductions from generation shifting for the states covered by this proposal.

It is equitable and reasonable to continue to use the same cost, performance, and timelines for EGU NO_x mitigation strategies that were determined for EGUs for the Federal Good Neighbor Plan¹⁴⁰ for the five additional states, as described in section III.D.4. of this document. The analysis of NO_x emissions controls was completed recently and there have been no meaningful changes in the factors considered since that analysis was completed.¹⁴¹ Table VI.B.1–1 summarizes the cost, performance, and availability dates based on the implementation timelines for the EGU NO_x mitigation strategies.

Under the analysis in the Federal Good Neighbor Plan and supported by technical information provided in the EGU NO_x Mitigation Strategies Final Rule TSD and its Addendum included

in the docket for this rulemaking, the EPA finds that the timeframe for optimizing existing SCR and SNCR controls is about 2 months or less, and the timeframe for upgrading combustion controls is about 6 months.

Additionally, for the same reasons described in the Federal Good Neighbor Plan, the EPA proposes that the first season for installing new SNCRs should be aligned with the first season of feasible installation for SCR, *i.e.*, the 2027 ozone season.¹⁴² Finally, for the same reasons that the EPA described in the Federal Good Neighbor Plan, the EPA proposes that SCR installation at EGUs can occur over a 36–48 month period, taking into account the fleetwide nature of the Federal Good Neighbor Plan (including this supplemental rulemaking to expand the Plan's coverage to five additional states, which considers emissions reductions commensurate with retrofitting SCR on only an additional seven units in Arizona).¹⁴³

TABLE VI.B.1–1—SUMMARY OF EGU NO_x MITIGATION STRATEGIES, REPRESENTATIVE COSTS, TIMELINES, AND APPLICABILITY

Mitigation strategy	Representative cost (2016\$)	Implementation timeline	First ozone season available for supplemental states	Unit applicability	NO _x emissions rate (lb/MMBtu)
Fully Operating Existing SCR (optimizing operating and idled SCR).	\$1,600/ton	<2 months	2025	Covered fossil-fired units with SCR.	Coal steam: 0.08; O/G Steam: 0.03; Combustion Turbine: 0.03; Combined Cycle: 0.012.
Installing State-Of-The-Art Combustion Controls.	\$1,600/ton	6 to 8 months	2025	Covered coal steam units lacking state-of-the-art combustion controls.	0.199.
Fully Operating Existing SNCR (optimizing operating and idled SNCR).	\$1,800/ton	<2 months	2025	Covered fossil-fired units with SNCR.	Up to a 25% reduction in emissions rate if SNCR idled.
Installing New SNCR	\$6,700/ton	16 months	2027	Covered CFB units of any size and other coal steam units under 100 MW lacking post-combustion NO _x controls ¹⁴⁴ .	Up to a 50% reduction in emissions rate for CFB units; up to a 25% reduction in emissions rate for other units.
Installing New SCR	\$11,000/ton (coal steam); \$7,700 (O/G steam).	36 to 48 months ...	2027 (with phase in over 2027 and 2028).	Covered coal steam units (except CFB) great than 100 MW; O/G Steam units at least 100 MW and with at least 150 tons NO _x emissions on average for the 2019 to 2021 ozone seasons.	0.05 for coal steam units; 0.03 for O/G steam units.

2. Non-EGUs

For the Federal Good Neighbor Plan, the EPA developed an analytical framework to facilitate decisions about which industries and emissions unit types in the non-electric generating unit “sector” may have a share of upwind states’ significant contribution to

nonattainment or interference with maintenance of the 2015 ozone NAAQS in other states. A February 28, 2022 memorandum documents the analytical framework that the EPA used to initially identify, through a regional-scale, multistate screening assessment (Screening Assessment), industries and emissions unit types for which there

appeared to be cost-effective reductions having the greatest potential for air quality benefit in downwind states.¹⁴⁵ From this Screening Assessment, the EPA further developed its proposed set of emissions control strategies for non-EGUs that would fully eliminate significant contribution from the

¹³⁹ 88 FR 36731.

¹⁴⁰ 88 FR 36720–36732.

¹⁴¹ See the EGU NO_x Mitigation Strategies Final Rule TSD Addendum.

¹⁴² 88 FR 36726.

¹⁴³ 88 FR 36727.

¹⁴⁴ No units in Arizona, the only State in this proposal linked in 2026, meet this criterion, but the mitigation strategy is included in the table for completeness.

¹⁴⁵ The memorandum titled *Screening Assessment of Potential Emissions Reductions, Air Quality Impacts, and Costs from Non-EGU Emissions Units for 2026* is available in the docket here: <https://www.regulations.gov/document/EPA-HQ-OAR-2021-0668-0150>.

upwind states.¹⁴⁶ Following consideration of public comment, in the final Federal Good Neighbor Plan the EPA finalized emissions control requirements for certain non-EGU sources. The EPA prepared a memorandum summarizing the emissions unit types, applicability criteria, emissions limits, estimated number of emissions units captured by the applicability criteria, and estimated emissions reductions and costs.¹⁴⁷ The EPA updated its technical analysis of non-EGU industry sectors and responded to public comments.¹⁴⁸ The final Federal Good Neighbor Plan established a uniform set of emissions control requirements for non-EGU sources in nine industries for each of the 20 states for which the EPA found continuing contribution at or above 1 percent of the NAAQS through the 2026 ozone season. *See generally* 88 FR at 36817–38.

As with its EGU analysis at Step 3, the EPA finds that it is equitable and reasonable to extend these same findings for the relevant non-EGU sources in the State of Arizona, which is the only state covered in this action for which the EPA continues to find a continuing contribution at or above 1 percent of the NAAQS through the 2026 ozone season. Several points that the EPA observed in the Federal Good Neighbor Plan bear emphasis in explaining why it is reasonable for Arizona's sources to be subject to the same Step 3 analysis and non-EGU control requirements as the other covered states. There is an equitable concern that supports an approach by which direct competitors within identified industries within the geography of linked upwind states are held to the same level of emissions performance, as this avoids the potential

for emissions shifting or competitive disadvantages brought on by assigning transport obligations to individual sources that are not borne by their competitors in other linked upwind states. Thus, this has informed how the EPA has consistently approached assessing emissions control opportunities in prior ozone transport rulemakings, and in particular, the analysis of emissions control opportunities on an industry-wide basis. For example, in CSAPR, we focused on a single industry, the power sector (or EGUs), because we found that in general, across this industry, there were highly cost-effective emissions control opportunities compared to other industries (based on our assessment at that time). *See* 76 FR at 48249. Similarly, in the NO_x SIP Call, we also focused on assessing emissions-control opportunities by industry (using NAICS-code industry classifications as we do in this action), while recognizing that boilers are a unit type that could have cost-effective emissions reductions across multiple industries (as we again recognize in this action). *See* 63 FR at 57399. The EPA explained in the NO_x SIP Call that this approach “assure[d] equity among the various source categories and the industries they represent,” *id.*

It was precisely this analytical framework that the Supreme Court upheld in *EME Homer City*, noting the “thorny causation problem” of interstate pollution transport, 572 U.S. at 514, the need to account for “the vagaries of the wind,” *id.* at 497, and the complexity of allocating responsibility among potentially large groups of states who may each contribute to one another's air quality problems as well as to multiple other states in varying degrees, *id.* 514–16.

Applying these principles here, the EPA views it as reasonable to conclude that the Screening Assessment methodology continues to serve as a reasonable and reliable method for distinguishing potentially impactful industries from non-impactful industries in Arizona, just as in the other states for purposes of defining good neighbor obligations for the 2015 ozone NAAQS in the context of a FIP. The Screening Assessment identified nine out of approximately 40 industries for further evaluation. That these were found to be the nine potentially most impactful industries is not surprising, as each of these industries typically involve large-scale fossil-fuel combustion as part of their manufacturing or other processes, have historically had high NO_x emissions as a result, and are projected to continue to have relatively high NO_x emissions into the future. For existing as well as any new sources that come to be located in Arizona, it therefore makes sense to require these sources to meet the same emissions control requirements that the same types of sources are subject to in the covered states that have been found to have non-EGU emissions that significantly contribute to other states' problems attaining and maintaining the 2015 ozone NAAQS.

The EPA therefore proposes to apply the same Step 3 non-EGU analytical framework for Arizona as applied in the covered states whose sources are subject to these requirements. Table VI.B.2–1 summarizes the industries, emissions unit types, and applicability requirements, and Table VI.B.2–2 summarizes the industries, emissions unit types, form of proposed emissions limits, and proposed emissions limits.

TABLE VI.B.2–1—SUMMARY OF INDUSTRIES, NON-EGU EMISSIONS UNIT TYPES, AND APPLICABILITY REQUIREMENTS

Industry	Emissions unit type	Applicability requirements
Pipeline Transportation of Natural Gas	Reciprocating Internal Combustion Engines.	Nameplate rating of ≥1000 braking horsepower (bhp).
Cement and Concrete Product Manufacturing	Kilns	Directly emits or has the potential to emit 100 tons per year (tpy) or more of NO _x .
Iron and Steel Mills and Ferroalloy Manufacturing	Reheat Furnaces	Directly emits or has the potential to emit 100 tpy or more of NO _x .
Glass and Glass Product Manufacturing	Furnaces	Directly emits or has the potential to emit 100 tpy or more of NO _x .
Iron and Steel Mills and Ferroalloy Manufacturing; Metal Ore Mining; Basic Chemical Manufacturing; Petroleum and Coal Products Manufacturing; Pulp, Paper, and Paperboard Mills.	Boilers	Design capacity of ≥100 mmBtu/hr.

¹⁴⁶ See Non-EGU Sectors Technical Support Document for the Proposed Rule, available at <https://www.regulations.gov/document/EPA-HQ-OAR-2021-0668-0145>.

¹⁴⁷ The memorandum titled *Summary of Final Rule Applicability Criteria and Emissions Limits for*

Non-EGU Emissions Units, Assumed Control Technologies for Meeting the Final Emissions Limits, and Estimated Emissions Units, Emissions Reductions, and Costs is available in the docket here: <https://www.regulations.gov/document/EPA-HQ-OAR-2021-0668-0956>.

¹⁴⁸ See Non-EGU Sectors Technical Support Document for the Final Rule, available at <https://www.regulations.gov/document/EPA-HQ-OAR-2021-0668-1110>.

TABLE VI.B.2–1—SUMMARY OF INDUSTRIES, NON-EGU EMISSIONS UNIT TYPES, AND APPLICABILITY REQUIREMENTS—Continued

Industry	Emissions unit type	Applicability requirements
Solid Waste Combustors and Incinerators	Combustors or Incinerators	Design capacity ≥250 tons of waste/day.

TABLE VI.B.2–2—SUMMARY OF NON-EGU INDUSTRIES, EMISSIONS UNIT TYPES, FORM OF PROPOSED EMISSIONS LIMITS, AND PROPOSED EMISSIONS LIMITS

Industry	Emissions unit type	Form of proposed emissions limits	Proposed emissions limits
Pipeline Transportation of Natural Gas	Reciprocating Internal Combustion Engines.	Grams per horsepower per hours (g/hp-hr).	Four Stroke Rich Burn: 1.0 g/hp-hr; Four Stroke Lean Burn: 1.5 g/hp-hr; Two Stroke Lean Burn: 3.0 g/hp-hr.
Cement and Concrete Product Manufacturing	Kilns	Pounds per ton (lbs/ton) of clinker.	Long Wet: 4.0 lb/ton; Long Dry: 3.0 lb/ton; Preheater: 3.8 lb/ton; Precalciner: 2.3 lb/ton; Preheater/Precalciner: 2.8 lb/ton.
Iron and Steel Mills and Ferroalloy Manufacturing.	Reheat Furnaces	lbs/mmBtu ^a	Test and set limit based on installation of Low-NO _x Burners.
Glass and Glass Product Manufacturing	Furnaces	lbs/ton glass produced	Container Glass Furnace: 4.0 lb/ton; Pressed/Blown Glass Furnace: 4.0 lb/ton; Fiberglass Glass Furnace: 4.0 lb/ton; Flat Glass Furnace: 7 lb/ton.
Iron and Steel Mills and Ferroalloy Manufacturing; Metal Ore Mining; Basic Chemical Manufacturing; Petroleum and Coal Products Manufacturing; Pulp, Paper, and Paperboard Mills.	Boilers	lbs/mmBtu ^a	Coal: 0.20 lb/mmBtu; Residual Oil: 0.20 lb/mmBtu; Distillate Oil: 0.12 lb/mmBtu; Natural Gas: 0.08 lb/mmBtu.
Solid Waste Combustors and Incinerators	Combustors or Incinerators.	ppmvd on a 24-hour averaging period and ppmvd on a 30-day averaging period.	110 ppmvd on a 24-hour averaging period; 105 ppmvd on a 30-day averaging period.

^a Heat input limit.

C. Control Stringencies Represented by Cost Threshold (\$ per Ton) and Corresponding Emissions Reductions

1. EGUs

For EGUs, as discussed in section VI.A. of this document, the multi-factor test considers increasing levels of uniform control stringency in combination with considering total NO_x reduction potential and corresponding air quality improvements. The EPA evaluated EGU NO_x emissions controls

that are widely available (described previously in section VI.B.1. of this document), that were assessed in previous rules to address ozone transport, and that have been incorporated into State planning requirements to address ozone nonattainment.

This analysis generated a selected representative cost threshold of \$11,000 per ton, associated with the retrofit of SCR on coal-fired EGUs currently

lacking that technology. 88 FR at 36745. All cost values discussed in this section for EGUs are in 2016 dollars.¹⁴⁹

The following tables summarize the emissions reduction potentials (in ozone season tons) from these emissions controls across the affected jurisdictions. Table VI.C.1–1 focuses on near-term emissions controls while Table VI.C.1–2 includes emissions controls with extended implementation timeframes.

TABLE VI.C.1–1—EGU OZONE-SEASON EMISSIONS AND REDUCTION POTENTIAL (TONS)—NEAR TERM *

State	Baseline 2025 OS NO _x	Reduction potential (tons) for varying levels of technology inclusion		
		SCR optimization	SCR optimization + combustion control upgrades	SCR/SNCR optimization + combustion control upgrades
Arizona	8,479	84	153	284
Iowa	9,867	0	54	115
Kansas	5,510	747	747	747
New Mexico	2,241	31	31	31
Tennessee	4,064	81	81	81

¹⁴⁹ The EPA used 2016 dollars in both the proposal and final Revised CSAPR Update RIA, as

well as the proposal and final Federal Good Neighbor Plan RIA, to be consistent with those

recent actions we continued to use 2016 dollars as the dollar year for presenting costs and benefits.

TABLE VI.C.1-1—EGU OZONE-SEASON EMISSIONS AND REDUCTION POTENTIAL (TONS)—NEAR TERM*—Continued

State	Baseline 2025 OS NO _x	Reduction potential (tons) for varying levels of technology inclusion		
		SCR optimization	SCR optimization + combustion control upgrades	SCR/SNCR optimization + combustion control upgrades
Total	30,162	943	1,066	1,257

* This analysis applies the same data sets, including relevant analytical year, as used in the Federal Good Neighbor Plan.

TABLE VI.C.1-2—EGU OZONE-SEASON EMISSIONS AND REDUCTION POTENTIAL (TONS)—EXTENDED IMPLEMENTATION

State	Baseline 2026 OS NO _x	Reduction potential (tons) for varying levels of technology inclu- sion			
		SCR optimization	SCR optimization + combustion control upgrades	SCR/SNCR optimization + combustion control upgrades	SCR/SNCR optimization + combustion control upgrades + SCR/SNCR retrofits
Arizona	6,098	84	153	284	2,085
Iowa	9,773	0	0	60	5,747
Kansas	5,510	747	747	747	2,398
New Mexico	2,038	31	31	31	361
Tennessee	4,064	81	81	81	81
Total	27,484	943	1,012	1,203	10,672

* This analysis applies the same data sets, including relevant analytical year, as used in the Federal Good Neighbor Plan.

2. Non-EGUs

As detailed in the memorandum titled, *Summary of Final Rule Applicability Criteria and Emissions Limits for Non-EGU Emissions Units, Assumed Control Technologies for Meeting the Final Emissions Limits, and Estimated Emissions Units, Emissions Reductions, and Costs*¹⁵⁰ prepared for the Federal Good Neighbor Plan, the EPA uses the 2019 emissions inventory, the list of emissions units estimated to be captured by the applicability criteria, the assumed control technologies that would meet the emissions limits, and information on control efficiencies and default cost/ton values from the control measures database¹⁵¹ to estimate NO_x emissions reductions and costs for this proposal. The estimates using the 2019 inventory and information from the control measures database identify proxies for emissions units, as well as emissions reductions, and costs

associated with the assumed control technologies that would meet the emissions limits. Emissions units subject to the proposed rule emissions limits may differ from those estimated in this assessment, and the estimated emissions reductions from and costs to meet the proposed rule emissions limits may also differ from those estimated in this assessment. The costs do not include monitoring, recordkeeping, reporting, or testing costs. As with the analysis for non-EGUs described in section VI.B.2. of this document, this proposal simply applies the same analysis that was conducted for these industries in the Federal Good Neighbor Plan, considering data specific to the one State included in this action, Arizona, that is proposed to be subject to the Federal Good Neighbor Plan's non-EGU emissions control requirements.

Table VI.C.2-1 of this document summarizes the industries, estimated

emissions unit types, and assumed control technologies that meet the proposed emissions limits. Table VI.C.2-2 of this document summarizes the industries, estimated emissions unit types, assumed control technologies that meet the proposed emissions limits, and the estimated number of control installations in Arizona. Table VI.C.2-3 summarizes the industries, estimated emissions unit types, assumed control technologies that meet the proposed emissions limits, annual costs (2016\$), and ozone season emissions reductions. The average cost per ton is \$5,457 and is estimated using annual emissions. As the EPA discussed in the Federal Good Neighbor Plan, the cost estimates for all non-EGU industries were generally commensurate with the representative uniform cost threshold of \$11,000 per ton selected for EGUs. *See* 88 FR at 36746–47.

¹⁵⁰ Available in the docket here: <https://www.regulations.gov/document/EPA-HQ-OAR-2021-0668-0956>.

¹⁵¹ More information on the control measures database can be found here: <https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/cost-analysis-modelstoools-air-pollution>.

economic-and-cost-analysis-air-pollution-regulations/cost-analysis-modelstoools-air-pollution.

TABLE VI.C.2-1—SUMMARY OF NON-EGU INDUSTRIES, EMISSIONS UNIT TYPES, ASSUMED CONTROL TECHNOLOGIES THAT MEET PROPOSED EMISSIONS LIMITS

Industry	Emissions unit type	Assumed control technologies that meet proposed emissions limits
Pipeline Transportation of Natural Gas	Reciprocating Internal Combustion Engines.	Layered Combustion (2-cycle Lean Burn) ^a ; SCR (4-cycle Lean Burn); NSCR (4-cycle Rich Burn).
Cement and Concrete Product Manufacturing	Kilns	SNCR.
Iron and Steel Mills and Ferroalloy Manufacturing	Reheat Furnaces	LNB.
Glass and Glass Product Manufacturing	Furnaces	LNB.
Iron and Steel Mills and Ferroalloy Manufacturing	Boilers	LNB + FGR (Natural Gas, No Coal or Oil).
Metal Ore Mining	SCR (Any Coal, Any Oil).
Basic Chemical Manufacturing
Petroleum and Coal Products Manufacturing
Pulp, Paper, and Paperboard Mills
Solid Waste Combustors and Incinerators	Combustors or Incinerators	ANSCR ^b ; LN tm and SNCR ^{b,c} .

^aSome emissions units, or engines, in the 2019 inventory had Source Classification Codes indicating that the units were reciprocating without specifying the type of engine. The EPA assumed Non-Selective Catalytic Reduction (NSCR) or layered combustion as the control for these emissions units.

^b*Municipal Waste Combustor Workgroup Report*, prepared by the Ozone Transport Commission Stationary and Area Sources Committee, Revised April 2022.

^cCovanta has developed a proprietary low NO_x combustion system (LNTM) that involves staging of combustion air. The system is a trademarked system and Covanta has received a patent for the technology.

TABLE VI.C.2-2—SUMMARY OF NON-EGU INDUSTRIES, EMISSIONS UNIT TYPES, ASSUMED CONTROL TECHNOLOGIES THAT MEET PROPOSED EMISSIONS LIMITS, ESTIMATED NUMBER OF CONTROL INSTALLATIONS *

Industry/industries	Emissions unit type	Assumed control technologies that meet proposed emissions limits	Estimated number of existing units per assumed control
Pipeline Transportation of Natural Gas ...	Reciprocating Internal Combustion Engines.	NSCR or Layered Combustion (Reciprocating). Layered Combustion (2-cycle Lean Burn). SCR (4-cycle Lean Burn) NSCR (4-cycle Rich Burn) 6

* This table is limited to existing covered non-EGU unit types located in the State of Arizona. This does not reflect a final determination that identified units, or any unidentified units meet or do not meet the applicability criteria of the proposed rule.

TABLE VI.C.2-3—SUMMARY OF NON-EGU INDUSTRIES, EMISSIONS UNIT TYPES, ASSUMED CONTROL TECHNOLOGIES, ESTIMATED TOTAL ANNUAL COSTS (2016\$), OZONE SEASON NO_x EMISSIONS REDUCTIONS IN 2026 *

Industry/industries	Emissions unit type	Assumed control technologies that meet proposed emissions limits	Annual costs (2016\$)	Ozone season emissions reductions
Pipeline Transportation of Natural Gas.	Reciprocating Internal Combustion Engine.	Layered Combustion (2-cycle Lean Burn).	4,309,893	329

* This table is limited to existing covered non-EGU unit types located in the State of Arizona. This does not reflect a final determination that identified units, or any unidentified units meet or do not meet the applicability criteria of the proposed rule.

D. Assessing Cost, EGU and Non-EGU NO_x Reductions, and Air Quality

As described in section V.A. of the Federal Good Neighbor Plan preamble, to determine the emissions that are significantly contributing to nonattainment or interfering with maintenance, the EPA applied the multi-factor test to EGUs and non-EGUs on separate but parallel tracks, considering for each the relationship of cost, available emissions reductions, and downwind air quality impacts. Specifically, for each sector, the EPA

finalized a determination regarding the fact that a uniform NO_x control stringency was appropriate and identified an appropriate level of uniform NO_x control stringency that would eliminate significant contribution from each upwind state. Based on the air quality results presented in section V.D. of the Federal Good Neighbor Plan preamble, the EPA found that the emissions control strategies that were identified and evaluated in sections V.B. and V.C. of the Federal Good Neighbor Plan preamble were cost-effective and

delivered meaningful air quality benefits through projected reductions in ozone levels across the linked downwind nonattainment and maintenance receptors in the relevant analytic years 2023 and 2026. Further, the EPA found the emissions control strategies in upwind states that would deliver these benefits to be widely available and in use at many other similar EGU and non-EGU facilities throughout the country, particularly in those areas that have historically or now continue to struggle to attain and

maintain the 2015 ozone NAAQS. As described in the Federal Good Neighbor Plan, for this regional pollutant (*i.e.*, ozone), for this NAAQS (*i.e.*, 2015 ozone), applying these emissions control strategies on a uniform basis across all linked upwind states constituted an efficient and equitable solution to the problem of allocating upwind-state responsibility for the elimination of significant contribution. *See* 88 FR at 36741.

The EPA finds that this solution should appropriately be extended to apply to the five remaining states addressed in this rulemaking. This uniform regional approach applying the levels of stringency determined in the Federal Good Neighbor Plan is in keeping with the uniform stringency approach that the EPA has applied across linked upwind states in its ozone transport rulemakings beginning with the NO_x SIP Call. The EPA finds that this approach continues to effectively address the “thorny” causation problem of interstate pollution transport for regional-scale pollutants like ozone that transport over large distances and are affected by the vagaries of meteorology. *EME Homer City*, 572 U.S. at 514–16. It requires the most impactful sources in each State that has been found to contribute to ozone problems in other states to come up to minimum standards of environmental performance based on demonstrated NO_x pollution-control technology. *Id.* at 519. As described in section V. of the Federal Good Neighbor Plan, when the effects of these emissions reductions are assessed collectively across the hundreds of EGU and non-EGU industrial sources that are subject to that rule, the cumulative improvements in ozone levels at downwind receptors, while they may vary to some extent, are both measurable and meaningful and will assist downwind areas in attaining and maintaining the 2015 ozone NAAQS. In this rule, we find that in these five additional states, there are emissions reductions available at the costs and control levels identified in the Federal Good Neighbor Plan and that these emissions reductions will likewise play a part in the meaningful air quality improvements that will assist downwind areas in attaining and maintaining the 2015 ozone NAAQS and ensure that linked upwind states are held to resolving their fair share of the problem.

As discussed in the following subsections, the EPA has evaluated the air quality effects of the different emissions control strategies identified. The receptors show measurable improvement in air quality at each

incremental control stringency, up to and including the selected emissions control strategies for EGUs and non-EGUs. These analytic findings further confirm that the selected control stringency applied in the Federal Good Neighbor Plan for 23 states is also the appropriate control stringency to eliminate significant contribution for the 2015 ozone NAAQS for these additional five states. In this proposal, for the states specifically included, the EPA also evaluates whether the proposal results in over-control by evaluating if an upwind State is linked solely to downwind air quality problems that could have been resolved at a lower cost threshold, or if an upwind State could have reduced its emissions below the 1 percent of NAAQS air quality contribution threshold at a lower cost threshold than identified in the Federal Good Neighbor Plan. The Agency finds no overcontrol from this proposal.

1. EGU and Non-EGU Cost and Emissions Reductions Assessment

As described in section VI.A. of this document, in Step 3, the multifactor test considers cost and air quality factors. In addition, in this proposed action the EPA continues to apply its longstanding approach of considering uniform level of NO_x control stringency as foundational to the identification of emissions that significantly contribute or interfere with maintenance of the ozone NAAQS, in light of the regional-scale, meteorological-variability, and long-range transport aspects of the ozone pollution problem. Thus, at a foundational level, the EPA views it as fundamentally equitable, efficient, and workable to extend the same emissions control strategies found necessary to eliminate significant contribution from 23 states already covered by the Federal Good Neighbor Plan to these five additional states. *See EME Homer*, 572 U.S. at 524.

As described in section VI.A. of this document, in addition to being cost-effective on a cost per ton basis, the EPA’s determination at Step 3 for both EGUs and non-EGUs is also informed by the overall level of emissions reductions that will be achieved and the effect those reductions are projected to have on air quality at the downwind receptors. The EPA also explained in the Federal Good Neighbor Plan that, for EGUs, the EPA is also influenced by the fact that the emissions control strategies for EGUs are generally well-demonstrated to be achieved in practice at many existing units, as established through our review of the controls currently installed on the fleet of

existing EGUs (*see* 88 FR at 36680). For non-EGUs, the EPA is also influenced by the fact that the emissions control strategies for non-EGUs are generally well demonstrated to be achieved in practice at many existing units, as established through our review of consent decrees, permits, Reasonably Available Control Technologies determinations, and other data sources (*see* 88 FR at 36661).

2. Step 3 Air Quality Assessment Methodology

As described in the Federal Good Neighbor Plan, to assess the air quality impacts of the various control stringencies at downwind receptors for the purposes of Step 3 in that rule, the EPA evaluated changes resulting from the emissions reductions associated with the identified emissions controls in each of the upwind states, as well as assumed corresponding reductions of similar stringency in the downwind State containing the receptor to which they are linked. By applying these emissions reductions to the State containing the receptor, the EPA assumed that the downwind State will implement (if it has not already) an emissions control stringency for its sources that is comparable to the upwind control stringency that was applied. Consequently, the EPA accounted for the downwind State’s “fair share” of the responsibility for resolving a nonattainment or maintenance problem as a part of the over-control evaluation.¹⁵² As a result, the EPA estimated the air quality design values (both average and maximum design values) under both the base and control scenarios and, also, evaluated the air quality contributions from each State to each downwind monitor relative to the Step 2 contribution threshold. In this supplemental rule, for the Step 3 and over-control evaluations, the EPA applied the same framework using the data and tools from the Federal Good Neighbor Plan (*see* the Good Neighbor Plan Ozone Transport Policy Analysis Final Rule TSD for details). As described in the next section, the EPA examined whether its findings in the Federal Good Neighbor Plan regarding stringency and overcontrol were robust to the updated

¹⁵² For EGUs, the analysis for the Connecticut receptors in the Federal Good Neighbor Plan shows no EGU reduction potential in Connecticut from the emissions reduction measures identified given that State’s already low-emitting fleet; however, EGU reductions were identified in Colorado and these reductions were included in the over-control analysis.

geographic coverage inclusive of the states identified in this action.

As explained in section III.D.1. of this document, the EPA continues to use 2023 and 2026 as the analytical years to inform its evaluation of good neighbor obligations for these five additional states, since these years were selected and used in the Federal Good Neighbor Plan as aligned with the 2024 and 2027 attainment dates and to maintain consistency and ensure equity among all states. *See* 88 FR at 36749–50.

3. Results for Combined EGU and Non-EGU Air Quality Assessment

For 2023, the EPA examined the air quality effects of the emissions reduction potential associated with each EGU emissions control technology (summarized in section VI.C. of this document) in the Federal Good Neighbor Plan to arrive at an appropriate level of stringency. The EPA uses the same framework for this supplemental action, and similarly determined that (1) there are available emissions reductions from these additional states in 2023, (2) they have a beneficial impact on downwind air quality at identified receptors, and (3) the updated geography, when incorporated into the multi-factor test, supports the same stringency or over control findings in this action as that of the Federal Good Neighbor Plan. The EPA confirmed that the emissions reductions from the five states, in isolation and in combination with those from the states in the Federal Good Neighbor Plan, reduced ozone levels at downwind receptors. For 2023, the resulting average and maximum design values, adjusted relative to the modeled design values can be found in the Ozone Transport Policy Analysis Supplemental Proposed Rule TSD. The EPA confirmed that these emissions reductions also do not result in the air quality contributions for any of the supplemental states dropping below the Step 2 air quality contribution threshold to all monitors to which the State is linked (*see* the Ozone Transport Policy Analysis Supplemental Proposed Rule TSD for details). While the average improvement in downwind air quality improvement for these five states is expectedly smaller than that for the 22-state region of the Federal Good Neighbor Plan's EGU control program, so too are the expected emissions reductions. Importantly, for individual State and receptor linkages, downwind air quality improvement was found (*see* the Ozone Transport Policy Analysis Supplemental Proposed Rule TSD). Moreover, health benefits associated with just minor improvements in ozone

concentrations far exceed the cost of such mitigation measures.

Likewise, for 2026, the EPA examined the air quality effects of the emissions reduction potential associated with the EGU and non-EGU emissions control technologies (presented in sections IV.B. and VI.C. of this document). Arizona was the only State among the five states with more stringent measures applied in 2026 due to their continued expected linkage. The EPA confirmed that these emissions reductions, both individually and in combination with those from the states in the Federal Good Neighbor Plan, had impacts on the air quality at downwind receptors. For 2026, the resulting average and maximum design values, adjusted relative to the modeled design values, can be found in the Ozone Transport Policy Analysis Supplemental Proposed Rule TSD. The EPA confirmed that these emissions reductions also do not result in the air quality contributions from Arizona dropping below the Step 2 air quality contribution threshold for all of its remaining receptors (*see* the Ozone Transport Policy Analysis Supplemental Proposed Rule TSD for details).¹⁵³

4. Conclusions

Considering the cost and air quality factors described above, with respect to emissions reductions available in the near term, the EPA proposes that the 2023 control stringency for EGUs identified for 22 states in the Federal Good Neighbor Plan constitutes the emissions reductions that comprise each of these five states' interference with maintenance of the 2015 ozone NAAQS in other states. For all affected supplemental states, this control stringency reflects the optimization of existing post-combustion controls and installation of state-of-the-art NO_x combustion controls, which are widely available at a representative cost of \$1,800 per ton. The EPA's evaluation also shows that the effective emissions rate performance across affected EGUs

¹⁵³ The EPA's comprehensive Step 3 analysis for the Federal Good Neighbor Plan specifically evaluated all states contributing above the threshold to each individual monitor. This included each of the five supplemental states (Arizona, Iowa, Kansas, New Mexico, and Tennessee) even though they were not regulated in that rulemaking. These states had their emissions adjusted when their air quality contributions were greater than or equal to 1 percent of the NAAQS for each individual downwind monitor in that action. Thus, they were already aligned with EPA's GNP Step 3 conclusion even prior to their re-examination in this action. While the results below highlight the collective impact of the updated geography, consistent with the final GNP Step 3 analysis, the segmental air quality benefits pertaining to the emissions reductions from these five states can be found in the Ozone Transport Policy Analysis Supplemental Proposed TSD and corresponding files.

consistent with realization of these mitigation measures has substantial air quality benefits and does not over-control upwind states' emissions relative to either the downwind air quality problems to which they are linked at Step 1 or the 1 percent contribution threshold at Step 2. This strategy will fully resolve obligations for the states of Iowa, Kansas, New Mexico, and Tennessee.

Similarly, in the case of extended implementation control measures, the EPA proposes that the 2026 control stringencies for EGUs and non-EGUs finalized in the Federal Good Neighbor Plan constitute the emissions reductions that comprise the full elimination of Arizona's interference with maintenance of the 2015 ozone NAAQS in other states. For Arizona, this control stringency reflects the installation of new SCR post-combustion controls at coal steam sources greater than or equal to 100 Megawatts (MW) and for a more limited portion of the oil/gas steam fleet that had higher levels of emissions. As described in the Federal Good Neighbor Plan, for EGUs, in addition to the optimization of existing post-combustion controls and installation of state-of-the-art NO_x combustion controls these SCR retrofits are appropriate for Arizona's linkages which persist and interfere with downwind areas' ability to maintain the 2015 ozone NAAQS by the Serious nonattainment date (*i.e.*, through the 2026 ozone season) at \$11,000 and \$7,700 per ton respectively. This control stringency also includes the estimated emissions reductions from certain non-EGUs. These emissions reductions for non-EGU sources are estimated to cost an average of \$5,457/ton, which is approximately half the representative uniform cost threshold of \$11,000 per ton selected for EGUs.

Furthermore, the EPA's evaluation shows that the effective emissions rate performance across EGUs and non-EGUs consistent with the full realization of these mitigation measures reduces ozone levels at the receptors to which Arizona is linked and does not over-control Arizona's emissions in 2026 relative to either the downwind air quality problems to which it is linked at Step 1 or the 1 percent contribution threshold at Step 2.

VII. Regulatory Requirements and Implementation

A. Regulatory Requirements for EGUs

To implement the required emissions reductions from EGUs in Arizona, Iowa, Kansas, New Mexico, and Tennessee, the EPA in this rulemaking is proposing

to expand the geographic scope of the CSAPR NO_x Ozone Season Group 3 Trading Program (“Group 3 trading program”) to include sources in these five states. Refer to section VI.B.1. of the preamble of the Federal Good Neighbor Plan for a general discussion of the use of allowance trading programs to achieve required emissions reductions from the electric power sector and an overview of the Group 3 trading program’s enhancements to maintain the selected control stringency over time and to improve emissions performance at individual units.

The EPA is not proposing to alter the Group 3 trading program design elements finalized in the Federal Good Neighbor Plan. The EPA is proposing to extend the program and its design elements to apply to sources in these five additional states. These design elements include the methodology for determining preset State emissions budgets for the 2023–2029 control periods, the methodology for determining dynamic State emissions budgets for control periods in 2026 and onwards, the annual recalibration of the Group 3 allowance bank, the unit-specific backstop daily emissions rate, the unit-specific emissions limitations contingent on assurance level exceedances, and monitoring and reporting requirements. The EPA provided opportunity for comment on these design elements in the public comment period following the proposal of the Federal Good Neighbor Plan. Following feedback from many commenters throughout the country, the EPA finalized the design elements with some modifications, and section VI.B. of the Federal Good Neighbor Plan preamble provides robust discussion of changes made in response to comments. The EPA additionally carefully evaluated and comprehensively responded to comments in the Response to Comment document included in the Federal Good Neighbor Plan docket. In general, the Agency considers any issues associated with the application of the Group 3 Trading Program in these five additional states to be within the scope of this action. The EPA does not propose changes in the basic design elements that were finalized in the Federal Good Neighbor Plan and is not aware of any circumstances that would justify an alternative approach in extending these provisions to these five additional states. Throughout the remainder of this section, where the EPA has identified particular issues that are clearly within the scope of this proposal, it has noted its invitation to comment.

For the reasons explained in section VI.B.1. of this document, the EPA proposes that only the EGU NO_x strategies of fully operating existing SCRs and SNCRs, and upgrading to state-of-the-art combustion controls are possible for the 2025 ozone season. Based on an assumption that this proposed action may be finalized sometime in the summer of 2024, the first ozone season in which these strategies can be implemented is the 2025 ozone season.

Regarding the strategy of retrofitting SCR controls, as the EPA described in the Federal Good Neighbor Plan, the EPA proposes that SCR installation at EGUs can occur over a 36–48 month period, taking into account the fleetwide nature of the Federal Good Neighbor Plan. However, the Agency also recognizes that individual SCR installations at EGUs are capable of being completed on shorter timeframes (as little as 21 months), and this proposed action only analyzes SCR-retrofit potential on EGUs for a single state, Arizona. Recognizing that this proposal may be finalized sometime in the summer of 2024, the EPA proposes that some amount of SCR-retrofit potential could be accomplished by the start of the 2027 ozone season, which would be just shy of a 3-year time period. The EPA also recognizes that the Serious area attainment date falls on August 3, 2027, and that good neighbor obligations should be addressed, if at all possible, no later than this date. Taking all of these considerations into account, the EPA proposes that SCR retrofits at EGUs in Arizona can be phased in over two ozone seasons, 2027 and 2028. This generally aligns with the 36–48 month estimate in the Federal Good Neighbor Plan.

Thus, the EPA is proposing that EGU sources located in Arizona, Iowa, Kansas, New Mexico, and Tennessee (and Indian country within the states’ borders) will participate in the Group 3 trading program starting with the 2025 ozone season, which runs from May 1, 2025, to September 30, 2025, and continuing in each ozone season after 2025. Sources in Iowa, Kansas, and Tennessee (and Indian country within the states’ borders), which currently participate in the CSAPR NO_x Ozone Season Group 2 Trading Program (“Group 2 trading program”), would not be required to participate in the Group 2 trading program with respect to emissions occurring after 2024.¹⁵⁴ The

EPA invites comment on its proposed compliance start dates for these five states.

The remainder of this section discusses the potentially affected units and the changes the EPA is proposing to synchronize the integration and participation of sources in these five states into the Group 3 trading program.

1. Applicability and Tentative Identification of Newly Affected Units

The Group 3 trading program applies to any stationary, fossil-fuel-fired boiler or stationary, fossil fuel-fired combustion turbine located in a covered State (or Indian country within the borders of a covered state) and serving at any time on or after January 1, 2005, a generator with nameplate capacity of more than 25 MW producing electricity for sale, with exemptions for certain cogeneration units and certain solid waste incineration units. The complete text of the Group 3 trading program’s applicability provisions (including the exemptions) and the associated definitions can be found at 40 CFR 97.1004 and 40 CFR 97.1002, respectively.

The EPA is not proposing any changes to the Group 3 trading program’s applicability provisions in this rulemaking. The applicability criteria for the Group 2 and Group 3 trading programs are identical, with the result that any units in Iowa, Kansas, and Tennessee (including units in Indian country within the borders of such states) that are already subject to the Group 2 trading program would also become subject to the Group 3 trading program. Further, the EPA expects that any units in Arizona and New Mexico (including units in Indian country within the borders of such states) that are already subject to the Acid Rain Program under that program’s applicability criteria (*see* 40 CFR 72.6), would also meet the applicability criteria for the Group 3 trading program.

Because the applicability criteria for the Acid Rain Program and the Group 3 trading program are not identical, some units that are not subject to the Acid Rain Program could meet the applicability criteria for the Group 3 trading program. Using data reported to the U.S. Energy Information Administration, the EPA has identified nine sources in Arizona and New Mexico with a total of 23 units that do not currently report NO_x emissions and operating data to the EPA under the

¹⁵⁴ The EPA would consider these EGUs’ participation in the Group 3 trading program as satisfying their states’ good neighbor obligations with respect to the 2008 ozone NAAQS (and for

Tennessee, the 1979 and 1997 ozone NAAQS as well) to the same extent that the states’ obligations are currently being met through the EGUs’ participation in the Group 2 trading program.

Acid Rain Program but that appear to meet the applicability criteria for the Group 3 trading program. The units are listed in Table VII.A.1–1. For each of

these units, the table shows the estimated historical heat input and emissions data that the EPA proposes to use for the unit when determining State

emissions budgets if the unit is ultimately treated as subject to the Group 3 trading program.

TABLE VII.A.1–1—SELECTED POTENTIALLY AFFECTED EXISTING UNITS

State	Facility ID	Facility name	Unit ID	Unit type	Estimated ozone season heat input (mmBtu)	Estimated ozone season NO _x emissions rate (lb/mmBtu)
Arizona	141	Agua Fria	AF4	CT	15,443	0.346
Arizona	141	Agua Fria	AF5	CT	13,659	0.345
Arizona	141	Agua Fria	AF6	CT	13,659	0.375
Arizona	160	Apache	GT3	CT	633,453	0.135
Arizona	147	Kyrene	KY4	CT	2,317	0.106
Arizona	147	Kyrene	KY5	CT	5,326	0.499
Arizona	147	Kyrene	KY6	CT	5,326	0.322
Arizona	116	Ocotillo	GT1	CT	1,752,453	0.016
Arizona	116	Ocotillo	GT2	CT	1,752,453	0.006
Arizona	118	Saguaro	GT1	CT	284,976	0.161
Arizona	118	Saguaro	GT2	CT	284,976	0.049
Arizona	8068	Santan	ST1	CC	1,037,153	0.037
Arizona	8068	Santan	ST2	CC	1,037,153	0.067
Arizona	8068	Santan	ST3	CC	1,037,153	0.052
Arizona	8068	Santan	ST4	CC	1,037,153	0.036
Arizona	117	West Phoenix	1B	CC	1,064,206	0.446
Arizona	117	West Phoenix	2B	CC	1,064,206	0.444
Arizona	117	West Phoenix	3B	CC	1,064,206	0.053
Arizona	117	West Phoenix	GT1	CT	12,125	0.165
Arizona	117	West Phoenix	GT2	CT	12,125	0.806
Arizona	120	Yucca	GT3	CT	587,371	0.140
Arizona	120	Yucca	GT4	CT	587,371	0.018
New Mexico	2446	Maddox	2	CT	62,445	0.309

The EPA requests comment on which existing units in Arizona and New Mexico and Indian country within the borders of each State would or would not meet the applicability criteria for the Group 3 trading program. The EPA also requests comment, with supporting data, on whether the estimated historical heat input and emissions data identified for each unit in Table VII.A.1–1 are representative for the unit.

2. Preset State Emissions Budgets

The Group 3 trading program as revised in the Federal Good Neighbor Plan provides for both preset and dynamic State emissions budgets. Preset emissions budgets were determined in the rulemaking for all states for the control periods in the years through 2029, and dynamic emissions budgets are computed according to procedures set forth in 40 CFR 97.1010(a) for each control period starting with the 2026 control period. In the control periods for the years from 2026 through 2029, the emissions budget for each State will be

the higher of the preset emissions budget or the dynamic emissions budget computed for the State for that control period. The variability limit for each State for each control period is determined as a percentage of the State's emissions budget for the control period in accordance with 40 CFR 97.1010(e), and the State's assurance level for the control period is the sum of the emissions budget and the variability limit. This same system for determining State emissions budgets, variability limits, and assurance levels would also apply to the five states that would be added to the Group 3 trading program in this rulemaking.

In this proposal, the EPA is presenting the proposed preset State ozone season NO_x emissions budgets for covered EGUs in Arizona, Iowa, Kansas, New Mexico, and Tennessee for the control periods in 2025 through 2029. For all five states, starting with the 2025 control period, the State emissions budgets would reflect emissions reductions achievable through

optimization of installed controls and installation of new state-of-the-art combustion controls. In addition, for Arizona but not for the other four states, the emissions reductions achievable through the installation and operation of new SCR controls would be phased in starting with the preset and dynamic budgets for the 2027 control periods and would be fully reflected in the preset and dynamic budgets for 2028 and later control periods. As noted previously, the EPA is not proposing changes in the methodologies used to establish the preset or dynamic State emissions budgets, the variability limits, or the assurance levels. The EPA is not aware of any circumstances that would justify an alternative approach in extending these provisions to these five additional states. Rather, the EPA is requesting comment on the preset State ozone season NO_x emissions budgets calculated using these methodologies. The preset State emissions budgets for control periods 2025–2029 are presented in Table VII.A.2–1.

TABLE VII.A.2-1—PROPOSED PRESET STATE EMISSIONS BUDGETS, 2025–2029
[tons]

	2025	2026	2027	2028	2029
Arizona	8,195	5,814	4,913	3,949	3,949
Iowa	9,752	9,713	9,713	9,713	9,077
Kansas	4,763	4,763	4,763	4,763	4,763
New Mexico	2,211	2,008	2,008	2,008	2,008
Tennessee	3,983	3,983	2,666	2,130	1,198

3. Unit-Level Allowance Allocations

Under the Group 3 trading program, in advance of each control period, a portion of each State's emissions budget for the control period is reserved as a set-aside for potential allocation to new units and the unreserved portion of the budget is then allocated among the state's existing units. If there are existing units in areas of Indian country within a State's borders not subject to the State's SIP authority, allocations to those units are made through Indian country existing unit set-asides.¹⁵⁵ After each control period, the new unit set-aside is allocated among any units qualifying for allocations within the State's borders (including areas of Indian country) and any remaining allowances are reallocated among the existing units. In almost all cases, the allocations to set-asides, to existing units, and to new units are made according to procedures laid out in the regulations at 40 CFR 97.1010 through 97.1012. The exception is that for control periods where the final State emissions budgets are established in the related rulemaking—e.g., the 2025 control period—the set-asides and allocations to existing units are also established in the related rulemaking, using the same allocation procedure applicable to later control periods. This same system for allocating allowances from the Federal Good Neighbor Plan would also apply to the five states that would be added to the Group 3 trading program in this rulemaking.

Based on the same methodology used to determine the percentages of the budgets set aside for new units for other states in the Federal Good Neighbor Plan, the EPA is proposing that the percentages of the budgets set aside for new units for the five proposed additional states would be the default of 5 percent for each of the states for all control periods, except for Arizona for the control periods in 2025 and 2026,

for which the percentage would be 11 percent. The EPA is also presenting the proposed unit-level allocations to existing units in the newly added states for the 2025 control period. The methodology and procedures used to determine new unit set-aside percentages and unit-level allocations are described in section VI.B.9. of the preamble to the Federal Good Neighbor Plan and in the "Addendum to the Allowance Allocation Under the Final Rule TSD for the Federal Good Neighbor Plan" TSD available in the docket for this action. The EPA's allocations and allocation procedures apply for the 2025 control period, and, by default, for subsequent control periods unless and until a State or tribe provides state- or tribe-determined allowance allocations under an approved SIP revision or Tribal implementation plan.¹⁵⁶ The EPA is taking comment only on the data inputs (e.g., corrections to the heat input value used for a particular unit) used in applying the allowance allocation methodology for existing units and on the resulting existing unit allocations proposed for the five proposed additional states. The EPA is not proposing changes in the methodologies used for allowance allocation and for establishing set-asides determined in the Federal Good Neighbor Plan. The EPA is not aware of any circumstances that would justify an alternative approach in extending these provisions to these five additional states.

4. Timing Adjustments for Certain Trading Program Provisions

In general, sources in the proposed additional states would face the same compliance requirements as sources in states already covered by the Group 3 trading program, but the EPA is

proposing three exceptions. The first exception concerns the timing with which elements of the selected emissions control strategy are reflected in the State emissions budgets. As discussed in section VI. of this document, the EPA proposes to find that it is reasonable for the State emissions budgets to reflect emissions reductions achievable from new combustion controls starting in the 2025 control period and emissions reductions achievable from new SCR controls phased in over the 2027–2028 control periods. These proposed timing determinations, which are necessarily later than the corresponding timing determinations for sources in states already covered by the Group 3 trading program, would be reflected in the preset and dynamic State emissions budgets for the proposed additional states, as discussed in section VII.A.2. of this document.

The second exception concerns the timing of the application of the backstop daily NO_x emissions rate provisions. For units in the proposed additional states with existing SCR controls, the EPA proposes that these provisions would apply starting in the 2026 control period, which would be the units' second control period in the revised Group 3 trading program. For units in Arizona without existing SCR controls, the backstop rate provision would apply in the second control period in which such controls are operated, but not later than the 2030 control period. These proposed schedules would reflect the same principles used to determine the schedules for units with and without existing SCR controls in the states already in the program. The backstop rate provisions would not apply to units without existing SCR controls in Iowa, Kansas, New Mexico, or Tennessee (unless the units choose to install such controls, in which case the backstop rate provisions would apply starting in the second control period in which such controls are operated) because the emissions control stringency identified as appropriate for those states to address the states' good neighbor obligations

¹⁵⁵ The EPA is aware of four existing EGUs in Indian country that would be covered under this rulemaking's proposed expansion of the Group 3 trading program: South Point Units A and B in the Fort Mojave Reservation within Arizona's borders, and Four Corners Units 4 and 5 in the Navajo Reservation within New Mexico's borders.

¹⁵⁶ The options for states to submit SIP revisions that would replace the EPA's default allowance allocations are discussed in sections VII.C.1., VII.C.2., and VII.C.3. of this document. Similarly, for a covered area of Indian country not subject to a State's CAA implementation planning authority, a tribe could elect to work with the EPA under the Tribal Authority Rule to develop a full or partial Tribal implementation plan under which the tribe would determine allowance allocations that would replace the EPA's default allocations for subsequent control periods.

does not include the installation of new SCR controls.¹⁵⁷

The third exception concerns the timing of the application of the maximum controlled baseline provisions which potentially cap allowance allocations to individual units. For units in the proposed additional states with existing SCR controls, the EPA proposes that these provisions would apply starting in the 2025 control period, which would be the units' first full control period in the revised Group 3 trading program. For units in Arizona without existing SCR controls, the maximum controlled baseline provisions would apply starting with the 2028 control period, which would be the first year in which the Arizona State emissions budget would fully reflect the emissions reductions achievable through the installation of new SCR controls. Again, these proposed schedules would reflect the same principles used to determine the schedules for units with and without existing SCR controls in the states already in the program. The maximum controlled baseline provisions would not apply to units without existing SCR controls in Iowa, Kansas, New Mexico, or Tennessee (unless the units choose to install such controls) because the emissions control stringency identified for those states as necessary to address the states' good neighbor obligations does not include the installation of new SCR controls.¹⁵⁸

The EPA requests comment on the proposed timing of the backstop daily NO_x emissions rate provisions and the maximum controlled baseline provisions for sources in the proposed additional states.

5. Creation of an Additional Group 3 Allowance Bank for the 2025 Control Period and Adjustment to Bank Recalibration for the 2025 Control Period

In the Federal Good Neighbor Plan, the EPA created an initial bank of 2023 Group 3 allowances available to sources in states newly added to the Group 3 trading program by converting banked

2017–2022 Group 2 allowances. Similarly, in this rulemaking the EPA proposes to create an initial bank of 2025 Group 3 allowances available to sources in the proposed additional states by converting banked 2017–2024 Group 2 allowances. The target quantity of banked 2025 Group 3 allowances to be created would be 21 percent of the sum of the 2025 State emissions budgets of the newly added states. The allowances to be converted would be all 2017–2024 Group 2 allowances held in the facility accounts of sources in the newly added states as of the conversion date, which is proposed to be 45 days after the effective date of a final rule in this rulemaking. The conversion ratio would be the total quantity of 2017–2024 Group 2 allowances being converted divided by the target quantity of 2025 Group 3 allowances being created, but not less than 1.0.

The EPA's rationale for proposing to create an initial allowance bank available to the sources in newly added states is generally the same as the rationale for creating the similar bank under the Federal Good Neighbor Plan. The limited differences between the two bank creation processes are attributable to changes in circumstances and are fully consistent with that rationale. First, because the emissions reductions achievable through installation of combustion controls would be reflected in the budgets for the newly added States' first control period in the program, the allowance bank target would be based on the first year's budgets rather than the second year's budgets. Second, because the EPA expects that the effective date of a final rule will not fall partway through an ozone season, there is no need in this proposal to plan for prorating of the allowance bank target quantity. Finally, because the sources in the newly added states would represent a minority of the sources currently participating in the Group 2 trading program, this proposal would not convert Group 2 allowances held in general accounts. For further discussion of the rationale for the proposed bank creation, see section VI.B.12.b. of the Federal Good Neighbor Plan preamble.

In addition to providing for the creation of an initial Group 3 allowance bank through the conversion of banked Group 2 allowances, the EPA is also proposing an adjustment to the Group 3 trading program's bank recalibration provisions for the 2025 control period to coordinate those provisions with the proposed addition of the five additional states. Specifically, the EPA is proposing to exclude the five newly added states' 2025 budgets when

calculating the bank ceiling target used to determine whether any bank recalibration for the 2025 control period will occur. The reason for this proposed change is that because the initial bank creation process described in the preceding paragraphs of this section (section VII.A.5. of this document) would separately create a quantity of banked allowances for 2025 of up to 21 percent of the newly added states' emissions budgets, to ensure that the overall quantity of banked allowances available for use in the entire Group 3 trading program in the 2025 control period is no more than 21 percent of the emissions budgets of all states covered by the program in 2025, the bank ceiling target used in the bank recalibration process for other banked allowances carried over into the 2025 control period in the Group 3 trading program would need to be limited to 21 percent of the budgets for the states other than the newly added states. For 2026 and later control periods, the bank ceiling target will be calculated for all states in the Group 3 trading program using the State emissions budgets for all covered states.

The EPA requests comment on the proposed creation of an initial Group 3 allowance bank and the proposed adjustment to the Group 3 allowance bank recalibration for the 2025 control period.

B. Regulatory Requirements for Non-EGUs

As summarized in section II.B. of this document, the EPA finalized requirements for emissions unit types in the following nine non-EGU industries (industrial sources) in the Federal Good Neighbor Plan: RICE in Pipeline Transportation of Natural Gas; kilns in Cement and Cement Product Manufacturing; reheat furnaces in Iron and Steel Mills and Ferroalloy Manufacturing; furnaces in Glass and Glass Product Manufacturing; boilers in Iron and Steel Mills and Ferroalloy Manufacturing, Metal Ore Mining, Basic Chemical Manufacturing, Petroleum and Coal Products Manufacturing, and Pulp, Paper, and Paperboard Mills; and combustors and incinerators in Solid Waste Combustors and Incinerators. The EPA determined these are the most impactful types of units in the relevant industries and that emissions reductions are achievable with the control technologies identified in sections VI.C.1. through VI.C.6. of the Federal Good Neighbor Plan and further discussed in the Final Non-EGU Sectors TSD. The rationale behind the applicability criteria, emissions limits, and additional regulatory requirements for each industry can also be found in

¹⁵⁷ As discussed in section X.C. of this document, the EPA is proposing to make technical corrections to the backstop rate provisions to ensure that the provisions would not inadvertently apply to units without existing SCR controls in any State for which the EPA's identified emissions control stringency does not include the installation of new SCR controls.

¹⁵⁸ As discussed in section X.C. of this document, the EPA is proposing to make technical corrections to the maximum controlled baseline provisions to ensure that the provisions would not inadvertently apply to units without existing SCR controls in any State for which the EPA's identified emissions control stringency does not include the installation of new SCR controls.

sections VI.C.1. through VI.C.6. of the Federal Good Neighbor Plan. The emissions control requirements of the Federal Good Neighbor Plan for non-EGU sources apply only during the ozone season (May through September) each year.

In this document, the EPA proposes to extend these regulatory requirements to affected units within the State of Arizona under the same rationale provided in the Federal Good Neighbor Plan. These proposed FIP requirements for Arizona apply to both new and existing emissions units in the State. This approach will ensure that all new and existing emissions units in Arizona that meet the applicability criteria will be subject to the same good neighbor requirements that apply to new and existing units under the Federal Good Neighbor Plan for other covered states, in a manner that is wholly consistent with the determination of significant contribution and interference with maintenance at Step 3 (see section VI. of this document). Applying this same uniform set of control requirements will also avoid creating, inadvertently or intentionally, any incentives to shift production (and therefore emissions) from an existing non-EGU source to a new non-EGU source of the same type but lacking the relevant emissions control requirements either within a linked State or in another linked state, including the State of Arizona. The rationale behind the applicability criteria, emissions limits, and additional regulatory requirements for each industry can be found in the Federal Good Neighbor Plan.

The EPA does not propose to make any changes in the non-EGU requirements that were finalized in the Federal Good Neighbor Plan as applicable to this one additional state. (The EPA does propose to make certain corrections in the regulatory text as applicable in all states that are subject to the Federal Good Neighbor Plan's non-EGU provisions, as discussed in section X. of this document.) The EPA proposes to extend these requirements to cover one additional state, Arizona. The EPA is not aware of any circumstances that would justify an alternative approach in extending these provisions to Arizona, which were already finalized to apply in other covered states on a uniform basis. However, the public is invited to comment on the proposed application of these requirements in Arizona.

Similar to the EPA's adjustment in the compliance schedule for EGUs, the EPA proposes that compliance with non-EGU requirements in Arizona can be accomplished by the start of the 2027

ozone season. This is 1 year later than the onset of these compliance obligations for states that currently are subject to the Federal Good Neighbor Plan. This reflects findings in the Federal Good Neighbor Plan that all non-EGU emissions control strategies can generally be implemented within a 3-year timeframe. Three years from when this proposal may be finalized in 2024 roughly correlates to the 2027 ozone season. Respecting the potential need for compliance extensions beyond this ozone season, this proposal likewise includes the availability of compliance extensions under 40 CFR 52.40(d) (as well as the availability of alternative emissions limits under 40 CFR 52.40(e)). The dates associated with filing applications under these provisions, as well as for making other filings and demonstrations in association with compliance with the non-EGU requirements, are proposed to be adjusted from the dates finalized in the Federal Good Neighbor Plan, and generally are proposed to align with the 2027 ozone season. (The Agency anticipates and acknowledges that the dates associated for compliance in the Federal Good Neighbor Plan for other states where that rule is currently stayed pending judicial review will likewise need to be reviewed and adjusted through rulemaking action.) The Agency invites comment on its proposal that compliance with emissions limits for covered non-EGU sources in Arizona will be required beginning on May 1, 2027.

C. Submitting a SIP

Under the Federal Good Neighbor Plan, a State may submit a SIP at any time to address CAA requirements that are covered by a FIP, and if the EPA approves the SIP submission it would replace the FIP, in whole or in part, as appropriate. As discussed in this section, states may opt for one of several alternatives that the EPA has provided to take over all or portions of the FIP. However, as discussed in greater detail further in this section of the document, the EPA also recognizes that states retain the discretion to develop SIPs to replace a FIP under approaches that differ from those the EPA finalizes.

The EPA has established certain specialized provisions for replacing FIPs with SIPs within all the CSAPR trading programs, including the use of so-called "abbreviated SIPs" and "full SIPs," see 40 CFR 52.38(a)(4) and (5) and (b)(4), (5), (8), (9), (11), and (12); 40 CFR 52.39(e), (f), (h), and (i). For a State to remove all FIP provisions through an approved SIP revision, a State would need to address all required reductions

addressed by the FIP for that state, *i.e.*, reductions achieved through both EGU control and non-EGU control, as applicable to that state. Additionally, tribes in Indian country within the geographic scope of this rule may elect to work with the EPA under the Tribal Authority Rule to replace the FIP for areas of Indian country, in whole or in part, with a Tribal implementation plan or reasonably severable portions of a Tribal implementation plan.

Consistent with the options provided to states included in the Federal Good Neighbor Plan, under the FIPs for the five states in this proposed rule whose EGUs are required to participate in the CSAPR NO_x Ozone Season Group 3 Trading Program, the EPA proposes to offer "abbreviated" and "full" SIP submission options for states. An "abbreviated SIP" would allow a State to submit a SIP revision that establishes state-determined allowance allocation provisions replacing the default FIP allocation provisions but leaving the remaining FIP provisions in place. A "full SIP" would allow a State to adopt a trading program meeting certain requirements that allow sources in the State to continue to use the EPA-administered trading program through an approved SIP revision, rather than a FIP. In addition, as under the Federal Good Neighbor Plan and past CSAPR rulemakings, the EPA proposes that newly added states have the option to adopt state-determined allowance allocations for existing units for the second control period under this rule—in this case, the 2026 control period—through streamlined SIP revisions. See 76 FR 48326–48332 for additional discussion of full and abbreviated SIP options; see also 40 CFR 52.38(b).

1. SIP Option To Modify Allocations for 2026 Under EGU Trading Program

As with the start of past CSAPR rulemakings, the EPA proposes the option to allow a newly added State to use a similar process to submit a SIP revision establishing allowance allocations for existing EGU units in the State for the second control period of the new requirements, *i.e.*, in 2026, to replace the EPA-determined default allocations. A State would have to submit a letter to the EPA by 15 days after the effective date of a final rule in this rulemaking indicating its intent to submit a complete SIP revision by April 1, 2025. The SIP revision would provide, in an EPA-prescribed format, a list of existing units within the State and their allocations for the 2026 control period. If a State does not submit a letter of intent to submit a SIP revision, or if a State submits a timely

letter of intent but fails to submit a SIP revision, the EPA-determined default allocations would be recorded by July 1, 2025. If a State submits a timely letter of intent followed by a timely SIP revision that is approved, the approved SIP revision allocations would be recorded by October 1, 2025.

2. SIP Option To Modify Allocations for 2027 and Beyond Under EGU Trading Program

For the 2027 control period and later, the EPA also proposes that newly added states in the CSAPR NO_x Ozone Season Group 3 Trading Program could submit a SIP revision that makes changes only to the allowance allocation provisions while relying on the FIP for the remaining provisions of the EGU trading program.¹⁵⁹ This abbreviated SIP option would allow states to tailor the FIP to their individual choices while maintaining the FIP-based structure of the trading program. To ensure the availability of allowance allocations for units in any Indian country within a State not covered by the State's CAA implementation planning authority, if the State chose to replace the EPA's default allocations with state-determined allocations, the EPA would continue to administer any portion of each State emissions budget reserved as a new unit set-aside or an Indian country existing unit set-aside.

The SIP submission deadline for this type of revision would be December 1, 2025, if the State intends for the SIP revision to be effective beginning with the 2027 control period. For states that submit this type of SIP revision, the deadline to submit state-determined allocations beginning with the 2027 control period under an approved SIP would be June 1, 2026, and the deadline for the EPA to record those allocations would be July 1, 2026. Similarly, a State could submit a SIP revision beginning with the 2028 control period and beyond by December 1, 2026, with State allocations for the 2028 control period due June 1, 2027, and the EPA's recordation of the allocations due by July 1, 2027.

3. SIP Option To Replace the Federal EGU Trading Program With an Integrated State EGU Trading Program

For the 2027 control period and later, the EPA proposes that newly added states in the CSAPR NO_x Ozone Season Group 3 Trading Program could choose to replace the Federal EGU trading program with an integrated State EGU

trading program through an approved SIP revision.¹⁶⁰ Under this full SIP option, a State could submit a SIP revision that makes changes only to modify the EPA-determined default allocations while adopting identical provisions for the remaining portions of the EGU trading program. This SIP option would allow states to replace these FIP provisions with state-based SIP provisions while continuing participation in the larger regional trading program. As with the abbreviated SIP option discussed previously, to ensure the availability of allowance allocations for units in any Indian country within a State not covered by the State's CAA implementation planning authority, if the State chooses to replace the EPA's default allocations with state-determined allocations, the EPA would continue to administer any portion of each State emissions budget reserved as a new unit set-aside or an Indian country existing unit set-aside.

Deadlines for this type of SIP revision would be the same as the deadlines for abbreviated SIP revisions. For the SIP-based program to start with the 2027 control period, the SIP revision deadline would be December 1, 2025, the deadline to submit state-determined allocations for the 2027 control period under an approved SIP would be June 1, 2026, and the deadline for the EPA to record those allocations would be July 1, 2026, and so on.

4. SIP Revisions That Do Not Use the Trading Program

States can submit SIP revisions to replace the FIP that achieve the necessary EGU emissions reductions but do not use the CSAPR NO_x Ozone Season Group 3 Trading Program. For a transport SIP revision that does not use the CSAPR NO_x Ozone Season Group 3 Trading Program, the EPA would evaluate the transport SIP revision based on the particular control strategies selected and whether the strategies as a whole provide adequate and enforceable provisions ensuring that the necessary emissions reductions (*i.e.*, reductions equal to or greater than what the Group 3 trading program will achieve) will be achieved. To address the applicable CAA requirements, the SIP revision should include the following general elements: (1) a comprehensive baseline 2023 statewide NO_x emissions inventory (which includes existing control requirements), which should be

consistent with the 2023 emissions inventory that the EPA used to calculate the required State budget in this final proposed rule (unless the State can explain the discrepancy); (2) a list and description of control measures to satisfy the State emissions reduction obligation and a demonstration showing when each measure would be implemented to meet the 2025 and successive compliance deadlines; (3) fully-adopted State rules providing for such NO_x controls during the ozone season; (4) for EGUs larger than 25 MW, monitoring and reporting under 40 CFR part 75, and for other units, monitoring and reporting procedures sufficient to demonstrate that sources are complying with the SIP (*see* 40 CFR part 51, subpart K ("source surveillance" requirements)); and (5) a projected inventory demonstrating that State measures along with Federal measures will achieve the necessary emissions reductions in time to meet the 2025 and successive compliance deadlines (*e.g.*, enforceable reductions commensurate with installation of SCR on coal-fired EGUs by the 2027 ozone season). The SIPs must meet procedural requirements under the Act, such as the requirements for public hearing, be adopted by the appropriate State board or authority, and establish by a practically enforceable regulation or permit(s) a schedule and date for each affected source or source category to achieve compliance. Once the State has made a SIP submission, the EPA will evaluate the submission(s) for completeness before acting on the SIP submission. EPA's criteria for determining completeness of a SIP submission are codified at 40 CFR part 51, appendix V.

For further background information on considerations for replacing a FIP with a SIP, *see* the discussion in the final CSAPR rulemaking (76 FR 48326).

5. SIP Revision Requirements for Non-EGU or Industrial Source Control Requirements

Just as with the EGU requirements discussed in section VII.C.1.–4. of this document, the EPA's finalization of this proposed interstate ozone transport FIP for Arizona would in no way affect the ability of the State to submit, for review and approval, a SIP that replaces the requirements of the FIP with State requirements. To replace the non-EGU portion of the FIP in a state, the State's SIP submission must provide adequate provisions to prohibit NO_x emissions that contribute significantly to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state. The State SIP submission must demonstrate that the

¹⁵⁹ Under the Federal Good Neighbor Plan, states already covered by the Group 3 trading program already have this option, starting with the 2025 control period. *See* 40 CFR 52.38(b)(11).

¹⁶⁰ Under the Federal Good Neighbor Plan, states already covered by the Group 3 trading program already have this option, starting with the 2025 control period. *See* 40 CFR 52.38(b)(12).

emissions reductions required by the SIP would continue to ensure that significant contribution and interference with maintenance from that State has been eliminated through permanent and enforceable measures. The non-EGU requirements of the FIP would remain in place in each covered State until a State's SIP submission has been approved by the EPA to replace the FIP.

The most straightforward method for a State to submit a presumptively approvable SIP revision to replace the non-EGU portion of the FIPs for the State would be to provide a SIP revision that includes emissions limits at an equivalent or greater level of stringency than is specified for non-EGU sources meeting the applicability criteria and associated compliance assurance provisions for each of the unit types identified in section VI.C. of this document. However, states are also free to develop alternative approaches to eliminating significant contribution and interference with maintenance in other states, so long as they are shown to be equivalent to the Federal plan they replace. The Federal Good Neighbor Plan contains a more detailed discussion of factors and considerations associated with replacing a good neighbor FIP. *See* 88 FR at 36842–43.

D. Title V Permitting

As with the Federal Good Neighbor Plan, as well as other previous good neighbor rules, like the CSAPR, the CSAPR Update, and the Revised CSAPR Update, this proposed rule would not establish any permitting requirements independent of those under Title V of the CAA and the regulations implementing Title V, 40 CFR parts 70 and 71.¹⁶¹ All major stationary sources of air pollution and certain other sources are required to apply for title V operating permits that include emissions limitations and other conditions as necessary to ensure compliance with the applicable requirements of the CAA, including the requirements of the applicable SIP. CAA sections 502(a) and 504(a), 42 U.S.C. 7661a(a) and 7661c(a). The “applicable requirements” that must be addressed in title V permits are defined in the title V regulations (40 CFR 70.2 and 71.2 (definition of “applicable requirement”)).

The EPA anticipates that, given the nature of the units subject to this final rule, most if not all of the sources at which the units are located are already subject to title V permitting

requirements and already possess a title V operating permit. For sources subject to title V, the interstate transport requirements for the 2015 ozone NAAQS that are applicable to them under the FIPs proposed in this action would be “applicable requirements” under title V and therefore must be addressed in the title V permits. For example, EGU requirements concerning designated representatives, monitoring, reporting, and recordkeeping, the requirement to hold allowances covering emissions, the compliance assurance provisions, and liability, and for non-EGUs, the emissions limits and compliance requirements are, to the extent relevant to each source, “applicable requirements” that must be addressed in the permits.

Consistent with EPA's approach under the Federal Good Neighbor Plan, the applicable requirements resulting from the FIPs generally would have to be incorporated into affected sources' existing title V permits either pursuant to the provisions for reopening for cause (40 CFR 70.7(f) and 71.7(f)), significant modifications (40 CFR 70.7(e)(4)) or the standard permit renewal provisions (40 CFR 70.7(c) and 71.7(c)).¹⁶² For sources newly subject to title V that would be affected sources under the FIPs, the initial title V permit issued pursuant to 40 CFR 70.7(a) would address the final FIP requirements.

As was the case in the Federal Good Neighbor Plan, the new and amended FIPs would impose no independent permitting requirements and the title V permitting process would impose no additional burden on sources already required to be permitted under title V. More detailed title V permitting considerations for both EGUs and non-EGUs are provided in section VI.D. of the Federal Good Neighbor Plan.

VIII. Environmental Justice Considerations, Implications and Outreach

A. Environmental Justice

Demographic proximity analyses allow one to assess the potentially vulnerable populations residing nearby affected facilities as an indicator of exposure and the potential for adverse health impacts that may occur at a local scale due to economic activity at a given location including noise, odors, traffic, and emissions such as NO₂, covered

under this EPA action and not modeled elsewhere in this *EIA*.

Although baseline proximity analyses are presented here for the supplemental rule, several important caveats should be noted. In most areas, emissions are not expected to increase from the rulemaking, so most communities nearby affected facilities should experience decreases in exposure from directly emitted pollutants. However, facilities may vary widely in terms of the impacts on populations they already pose to nearby populations. In addition, proximity to affected facilities does not capture variation in baseline exposure across communities, nor does it indicate that any exposures or impacts will occur and should not be interpreted as a direct measure of exposure or impact. These points limit the usefulness of proximity analyses when attempting to answer question from EPA's Environmental Justice Technical Guidance.

Demographic proximity analyses were performed for two subsets of facilities affected by the supplemental rule:

- Electricity Generating Unit (EGU): Comparison of the percentage of various populations (race/ethnicity, age, education, poverty status, income, and linguistic isolation) living nearby covered EGU sources to average national levels.
- Non-EGU (non-electric generating units, or other stationary emissions sources): Comparison of the percentage of various populations (race/ethnicity, age, education, poverty status, income, and linguistic isolation) living nearby covered non-EGU sources to average national levels.

1. EGU Proximity Assessment

The current analysis identified all census blocks with centroids within a 5 km, 10 km and 50 km radius of the latitude/longitude location of each facility, and then linked each block with census-based demographic data.¹⁶³ The total population within a specific radius around each facility is the sum of the population for every census block within that specified radius, based on each block's population provided by the decennial Census.¹⁶⁴ Statistics on race,

¹⁶³ Five km and 50 km radii are the default distances currently used for proximity analyses. The 5 km distance is the shortest distance that should be chosen to avoid excessive demographic uncertainty and provides information on near-field populations. The 50 km distance offers a sub-regional perspective. The 10 km distance was added to this analysis as few to no people were within 5 km of some affected facilities.

¹⁶⁴ The location of the Census block centroid is used to determine if the entire population of the Census block is assumed to be within the specified radius. It is unknown how sensitive these results may be to different methods of population estimation, such as aerial apportionment.

¹⁶¹ Part 70 addresses requirements for State title V programs, and Part 71 governs the Federal title V program.

¹⁶² A permit is reopened for cause if any new applicable requirements (such as those under a FIP) become applicable to an affected source with a remaining permit term of 3 or more years. If the remaining permit term is less than 3 years, such new applicable requirements will be added to the permit during permit renewal. *See* 40 CFR 70.7(f)(1)(i) and 71.7(f)(1)(i).

ethnicity, age, education level, poverty status and linguistic isolation were obtained from the Census' 2015–2019 American Community Survey 5-year averages. These data are provided at the block group level. For the purposes of this analysis, the demographic characteristics of a given block group—that is, the percentage of people in different races/ethnicities, the percentage in different age groups (<18, 18–64, and >64), the percentage without a high school diploma, the percentage that are below the poverty level, and the percentage that are linguistically isolated—are presumed to also describe each census block located within that block group.

In addition to facility-specific demographics, the demographic composition of the total population within the specified radius (*e.g.*, 50 km) for all facilities as a whole was also computed (*e.g.*, all EGUs or all non-EGU facilities). In calculating the total populations, to avoid double-counting, each census block population was only counted once. That is, if a census block was located within the selected radius (*i.e.*, 50 km) for multiple facilities, the population of that census block was

only counted once in the total population. Finally, this analysis compares the demographics at each specified radius (*i.e.*, 5 km, 10 km, and 50 km) to the demographic composition of the nationwide population.

For this action, a demographic analysis was conducted for nine EGU facilities assumed to install additional controls at the 5 km, 10 km, and 50 km radius distances (Table VIII.A.1–1). Approximately 7 million people live within 50 km of these nine EGU facilities, representing roughly 2 percent of the 328 million total population of the U.S. Within 50km of EGU facilities, there is a higher Hispanic/Latino population than the national average (26 percent versus 19 percent) and a higher Native American population than the national average (1.9 percent versus 0.7 percent). Other demographics of the population within 50km of the EGU facilities are similar to the national averages. Approximately 166 thousand and 716 thousand people live within 5 km and 10 km of the EGU facilities, respectively. The demographic make-up of the population within 5 km and 10 km of EGU facilities are very similar. Within 5 km and 10 km of EGU

facilities, there is a higher Hispanic/Latino population than the national average (60 percent within 5 km and 53 percent within 10 km versus 19 percent nationwide) and a higher Native American population than the national average (5.5 percent within 5 km and 3.5 percent within 10 km versus 0.7 percent nationwide). The populations within 5 km and 10 km of EGU facilities have a higher percentage of people under the age of 18 compared to the national average (29 percent within both 5km and 10km versus 23 percent nationwide). The percent of people living below the poverty level is higher than the national average (24 percent within 5 km and 23 percent within 10 km versus 13 percent nationwide). The percent of people over the age of 25 without a high school diploma is higher than the national average (18 percent within 5 km and 16 percent within 10 km versus 12 percent nationwide), and the percent of people living in linguistic isolation is higher than the national average (12 percent within 5 km and 10 percent within 10 km versus 5 percent nationwide).

TABLE VIII.A.1–1—POPULATION DEMOGRAPHICS FOR THE NINE EGU FACILITIES ASSUMED TO INSTALL ADDITIONAL CONTROLS DUE TO THE SUPPLEMENTAL RULE

Demographic group	Percent (%) of population within each distance compared to the national average ¹			
	5 km	10 km	50 km	National average
Race/Ethnicity:				
White	23	28	59	60
African American	9	10	7	12
Native American	5.5	3.5	1.9	0.7
Other and Multiracial	3	5	6	8
Hispanic or Latino ²	60	53	26	19
Age:				
0–17 Years Old	29	29	24	23
18–64 Years Old	61	62	61	62
>=65 Years Old	9	9	15	16
Income:				
People Living Below the Poverty Level	24	23	14	13
Education:				
>= 25 Years Old Without a High School Diploma	18	16	8	12
Language:				
People Living in Linguistic Isolation	12	10	5	5
Total Population	165,712	716,296	6,742,898	328,016,242

¹ Demographic percentage is based on the Census' 2015–2019 American Community Survey 5-year averages, at the block group level, and include the 50 states, District of Columbia, and Puerto Rico. Total population is based on block level data from the 2010 Decennial Census.

² To avoid double counting, the “Hispanic or Latino” category is treated as a distinct demographic category for these analyses. 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.

2. Non-EGU Proximity Assessment

For this action, a demographic analysis was also conducted for two non-EGU facilities assumed to install additional controls at the 5 km, 10 km,

and 50 km radius distances (Table VIII.A.2–1). Approximately 218 thousand people live within 50 km of these two non-EGU facilities, representing roughly 0.07 percent of the 328 million total population of the U.S.

Within 50km of the two non-EGU facilities, there is a higher White population than the national average (72 percent versus 60 percent), and there is a higher Native American population than the national average (3.8 percent

versus 0.7 percent). There is also a higher population over the age of 65 than the national average (24 percent versus 16 percent). Approximately 200 and 3,000 people live within 5 km and 10 km of the non-EGU facilities, respectively. The demographic make-up of the population within 5 km and 10 km of non-EGU facilities are similar. Within 5 km and 10 km of non-EGU facilities, there is a higher White

population than the national average (87 percent within 5km and 88 percent within 10 km versus 60 percent nationwide) and there is a higher Native American population than the national average (2.2 percent within 5 km and 1.0 percent within 10 km versus 0.7 percent nationwide). Concerning the age distribution within 5 and 10km of the two non-EGU facilities, the percent of people aged 65 or older is higher than

the national average (31 percent within 5 km and 36 percent within 10 km versus 16 percent nationwide). Additionally, the percent of people living below the poverty level within 5 km and 10 km of the non-EGU facilities is higher than the national average (18 percent within 5 km and 17 percent within 10 km versus 13 percent nationwide).

TABLE VIII.A.2–1—POPULATION DEMOGRAPHICS FOR THE TWO NON-EGU FACILITIES ASSUMED TO INSTALL ADDITIONAL CONTROLS DUE TO THE SUPPLEMENTAL RULE

Demographic group	Percent (%) of population within each distance compared to the national average ¹			
	5 km	10 km	50 km	National average
Race/Ethnicity:				
White	87	88	72	60
African American	0	0	1	12
Native American	2.2	1.0	3.8	0.7
Other and Multiracial	4	4	5	8
Hispanic or Latino ²	7	7	19	19
Age:				
0–17 Years Old	5	6	17	23
18–64 Years Old	65	58	59	62
>=65 Years Old	31	36	24	16
Income:				
People Living Below the Poverty Level	18	17	14	13
Education:				
>=25 Years Old Without a High School Diploma	7	8	8	12
Language:				
People Living in Linguistic Isolation:	0	0	2	5
Total Population	204	3,193	218,256	328,016,242

¹ Demographic percentage is based on the Census' 2015–2019 American Community Survey 5-year averages, at the block group level, and include the 50 states, District of Columbia, and Puerto Rico. Total population is based on block level data from the 2010 Decennial Census.

² To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category for these analyses. 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.

For additional information on the EGU or non-EGU proximity analyses, see section VII.3. of the Federal Good Neighbor Plan as well as the memorandum *Analysis of Demographic Factors For Populations Living Near EGU and Non-EGU Facilities*, in the rulemaking docket.

B. Outreach

Prior to this proposal and prior to proposal of the EPA's Federal Good Neighbor Plan, the EPA initiated a public outreach effort to gather input from stakeholder groups likely to be interested in this action. Specifically, the EPA hosted an environmental justice webinar on October 26, 2021, to share information about the Federal Good Neighbor Plan and solicit feedback about potential environmental justice considerations. The webinar was attended by over 180 individuals representing State governments, federally recognized tribes, environmental NGOs, higher education

institutions, industry, and the EPA.¹⁶⁵ Participants were invited to comment during the webinar or provide written comments to a pre-regulatory docket. The webinar was recorded and distributed to attendees after the event. The key issues raised by interested parties is summarized in section VIII.C. of the EPA's proposed Good Neighbor Plan Rulemaking, and the EPA's response to these comments regarding environmental justice considerations are available in section 6 of the *Response To Comments* document for the Federal Good Neighbor Plan.^{166 167}

¹⁶⁵ This does not constitute the EPA's Tribal consultation under Executive Order 13175, which is described in section XI.F. of this document.

¹⁶⁶ 87 FR 20036 at 20153.

¹⁶⁷ "Federal "Good Neighbor Plan" for the 2015 Ozone National Ambient Air Quality Standards Response to Public Comments on Proposed Rule" at 837. Available in Docket ID No. EPA-HQ-OAR-2021-0668-1127.

IX. Costs, Benefits, and Other Impacts of the Proposed Rule

In the *EIA* for this action, the EPA estimated the health and climate benefits, compliance costs, and emissions changes that may result from the proposed rule for the analysis period 2025 to 2044. The estimated health and climate benefits and compliance costs are presented in detail in the *EIA*. The EPA notes that for EGUs the estimated benefits and compliance costs are directly associated with fully operating existing SCRs during ozone season; fully operating existing SNCRs during ozone season; installing state-of-the-art combustion controls; imposing a backstop emissions rate on certain units that lack SCR controls; and installing SCR and SNCR post-combustion controls. The EPA also notes that for non-EGUs the estimated health benefits and compliance costs are directly associated with installing controls to meet the NO_x emissions requirements

presented in section I.B. of this document.

For EGUs, the EPA analyzed this action's emissions budgets using uniform control stringency represented by \$1,800 per ton of NO_x (2016\$) in 2025 and \$11,000 per ton of NO_x (2016\$) in 2027. For non-EGUs, the EPA developed an analytical framework to determine which industries and

emissions unit types to include in a proposed Transport FIP for the 2015 ozone NAAQS transport obligations. A February 28, 2022, memorandum, titled "*Screening Assessment of Potential Emissions Reductions, Air Quality Impacts, and Costs from Non-EGU Emissions Units for 2026*," documents the analytical framework used to

identify industries and emissions unit types included in the proposed FIP.

Table IX–1 provides the projected 2025 through 2030, 2035, 2040, and 2044 EGU NO_x ozone season emissions reductions for the proposed rule. For additional information on emissions changes, *see* Table 3–7 and Table 3–8 in the *EIA*.

TABLE IX–1—EGU OZONE SEASON NO_x EMISSIONS AND EMISSIONS CHANGES (TONS) FOR THE BASELINE RUN AND PROPOSED RULE FROM 2025–2044

Ozone season NO _x (tons)	Total emissions		Change from baseline run
	Baseline	Proposal	
2025:			
5 States	23,701	22,243	– 1,458
Other States	234,186	234,186	0
Nationwide	257,887	256,428	– 1,459
2026:			
5 States	23,701	22,243	– 1,458
Other States	234,186	234,186	0
Nationwide	257,887	256,428	– 1,459
2027:			
5 States	18,270	17,012	– 1,258
Other States	189,571	189,583	12
Nationwide	207,840	206,595	– 1,245
2028:			
5 States	18,270	17,012	– 1,258
Other States	189,571	189,583	12
Nationwide	207,840	206,595	– 1,245
2029:			
5 States	18,270	17,012	– 1,258
Other States	189,571	189,583	12
Nationwide	207,840	206,595	– 1,245
2030:			
5 States	16,184	15,427	– 756
Other States	150,909	150,910	0
Nationwide	167,093	166,337	– 756
2035:			
5 States	5,967	5,453	– 513
Other States	94,061	94,053	– 8
Nationwide	100,028	99,506	– 521
2040:			
5 States	5,623	4,901	– 722
Other States	77,971	78,010	39
Nationwide	83,594	82,910	– 683
2044:			
5 States	5,271	4,549	– 722
Other States	71,506	71,506	0
Nationwide	76,778	76,055	– 722

Note: The 5 States include Arizona, Iowa, Kansas, New Mexico, and Tennessee. The Other States include the remaining states not covered by the proposal in the contiguous United States. Nationwide is the total of the 5 States and the Other States.

Table IX–2 provides a summary of the ozone season NO_x emissions reductions and costs for non-EGUs in Arizona

starting in 2028. We estimated the emissions reductions and costs for 2026 and assume compliance by 2028. The

analysis in the *EIA* assumes that the estimated reductions in 2028 will be the same in later years.

TABLE IX–2—SUMMARY OF NON-EGU INDUSTRIES, EMISSIONS UNIT TYPES, ASSUMED CONTROL TECHNOLOGIES, ESTIMATED TOTAL ANNUAL COSTS (2016\$), OZONE SEASON NO_x EMISSIONS REDUCTIONS

Industry/Industries	Emissions unit type	Assumed control technologies that meet proposed emissions limits	Annual costs (million 2016\$)	Ozone season emissions reductions (tons)
Pipeline Transportation of Natural Gas.	Reciprocating Internal Combustion Engine.	Layered Combustion (2-cycle Lean Burn).	4.3	329

For EGUs, the EPA analyzed ozone season NO_x emissions reductions and the associated costs to the power sector using IPM and its underlying data and inputs. For non-EGUs, the EPA prepared an assessment summarized in the memorandum titled *Non-EGU*

Applicability Requirements and Estimated Emissions Reductions and Costs Proposed Supplemental, and the memorandum includes estimated emissions reductions for the proposed rule.

Table IX–3 reflects the estimates of emissions reductions and the changes in

the cost of supplying electricity for the proposed rule for EGUs and estimates of complying with the emissions requirements for non-EGUs. The costs presented in Table IX–3 do not include monitoring, recordkeeping, and reporting costs.

TABLE IX–3—TOTAL ANNUAL ESTIMATED NO_x EMISSIONS REDUCTIONS (OZONE SEASON, TONS) AND COMPLIANCE COSTS (MILLION 2016\$), 2025–2044

	Emissions reductions (ozone season, tons)			Compliance costs (million 2016\$)		
	EGUs	Non-EGUs	Total	EGUs	Non-EGUs	Total
2025	1,459	1,459	\$1.0	\$1.0
2026	1,459	1,459	1.0	1.0
2027	1,245	1,245	3.4	3.4
2028	1,245	329	1,574	3.4	\$4.3	7.7
2029	1,245	329	1,574	3.4	4.3	7.7
2030	756	329	1,085	0.7	4.3	5.0
2035	513	329	842	0.7	4.3	5.0
2040	683	329	1,012	0.3	4.3	4.6
2044	722	329	1,051	0.7	4.3	4.6

For this proposed supplemental rule, the EPA monetizes the health benefits of avoided ozone and PM_{2.5}-attributable premature deaths and illnesses by

multiplying a benefit per ton coefficient by the expected State NO_x ozone season and primary PM_{2.5}, NO_x and SO₂ emissions reductions. The benefit per

ton calculations for EGUs and non-EGUs have been combined in Table IX–4.

TABLE IX–4—ESTIMATED MONETIZED HEALTH BENEFITS OF AVOIDED OZONE AND PM_{2.5}-ATTRIBUTABLE PREMATURE MORTALITY AND ILLNESS FOR THE PROPOSED RULE EMISSIONS REDUCTIONS (EGUS AND NON-EGUS), 2025–2044: MONETIZED BENEFITS QUANTIFIED AS SUM OF AVOIDED MORBIDITY HEALTH EFFECTS AND AVOIDED LONG-TERM OZONE AND PM_{2.5} MORTALITY

[3 Percent discount rate; million 2016\$]^{a b}

Year	Ozone	PM _{2.5}	Combined total
2025	\$16 and \$110	\$32 and \$69	\$48 and \$180.
2026	\$16 and \$110	\$32 and \$69	\$48 and \$180.
2027	\$14 and \$96	\$4.7 and \$9.9	\$19 and \$110.
2028	\$18 and \$140	\$8.3 and \$17	\$26 and \$160.
2029	\$18 and \$140	\$8.3 and \$17	\$26 and \$160.
2030	\$13 and \$99	\$5.4 and \$11	\$18 and \$110.
2031	\$13 and \$99	\$5.4 and \$11	\$18 and \$110.
2032	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2033	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2034	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2035	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2036	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2037	\$12 and \$95	\$4.9 and \$9.8	\$17 and \$100.
2038	\$14 and \$120	\$4.8 and \$9.5	\$19 and \$130.
2039	\$14 and \$120	\$4.8 and \$9.5	\$19 and \$130.
2040	\$14 and \$120	\$4.8 and \$9.5	\$19 and \$130.
2041	\$14 and \$120	\$4.8 and \$9.5	\$19 and \$130.
2042	\$14 and \$120	\$4.8 and \$9.5	\$19 and \$130.
2043	\$15 and \$130	\$6 and \$12	\$21 and \$140.
2044	\$15 and \$130	\$6 and \$12	\$21 and \$140.

^a Values rounded to two significant figures.

^b The benefits are associated with two point estimates from two different epidemiologic studies. The lower estimates includes ozone mortality estimated using the pooled Katsouyanni et al. (2009), the Zanobetti and Schwartz (2008) short-term risk estimates, and the Wu et al. (2020) long-term PM_{2.5} exposure mortality risk estimate. The higher estimates includes ozone mortality estimated using the Turner et al. (2016) long-term risk estimate and the Pope et al. (2019) long-term PM_{2.5} exposure mortality risk estimate. Health benefits are discounted at a rate of 3 and 7 percent over the SAB-recommended 20-year segmented lag. Individual values in the table are not further discounted for purposes of estimating a present value.

Table IX–5 shows the estimated monetary value of the estimated changes

in CO₂ emissions from EGUs expected to occur over 2025–2044 for this

proposed rule. The EPA estimated the dollar value of the CO₂-related effects

for each year between 2025 and 2044 by applying the SC-CO₂ estimates to the estimated changes in CO₂ emissions in the corresponding year.

TABLE IX-5—STREAM OF CLIMATE BENEFITS FROM EGU CO₂ EMISSIONS REDUCTIONS, 2025–2044
[Millions of 2016\$]

Year	Discount rate and statistic			
	5% Average	3% Average	2.5% Average	3% 95th percentile
2025	\$0.6	\$2.1	\$3.0	\$6.2
2026	0.6	2.1	3.1	6.3
2027	0.5	1.5	2.2	4.6
2028	0.5	1.5	2.3	4.7
2029	0.5	1.6	2.3	4.8
2030	0.5	1.7	2.5	5.2
2031	0.6	1.8	2.5	5.3
2032	0.0	–0.1	–0.2	–0.4
2033	0.0	–0.1	–0.2	–0.4
2034	0.0	–0.1	–0.2	–0.4
2035	0.0	–0.1	–0.2	–0.4
2036	0.0	–0.1	–0.2	–0.4
2037	0.0	–0.1	–0.2	–0.4
2038	–0.1	–0.3	–0.4	–0.8
2039	–0.1	–0.3	–0.4	–0.8
2040	–0.1	–0.3	–0.4	–0.8
2041	–0.1	–0.3	–0.4	–0.8
2042	–0.1	–0.3	–0.4	–0.8
2043	0.0	0.0	0.0	0.0
2044	0.0	0.0	0.0	0.0

Note: Individual values in the table are not further discounted for purposes of estimating a present value.

The EPA calculates the monetized net benefits of the proposed rule by subtracting the estimated monetized compliance costs from the estimated monetized health and climate benefits. The benefits include those to public health associated with reductions ozone and PM_{2.5} concentrations, as well as those to climate associated with reductions in GHG emissions. The EPA presents estimates of the PV of the monetized benefits and costs over the 20-year period 2025 to 2044. To calculate the PV of the social net-

benefits of the proposed rule, annual benefits and costs are discounted to 2023 at 3 percent and 7 discount rates as recommended by OMB's Circular A–4. The EPA also presents the EAV, which represents a flow of constant annual values that, had they occurred in each year from 2025 to 2044, would yield a sum equivalent to the PV. The EAV represents the value of a typical cost or benefit for each year of the analysis. Table IX–6 provides the comparison of benefits and costs in PV and EAV terms for the proposed rule.

Estimates in the table are presented as rounded values. For the 20-year period of 2025 to 2044, the PV of the net benefits, in 2016\$ and discounted to 2023, is \$270 and \$1,800 million when using a 3 percent discount rate and \$180 and \$1,100 million when using a 7 percent discount rate. The EAV is \$18 and \$120 million per year when using a 3 percent discount rate and \$17 and \$110 million when using a 7 percent discount rate.

TABLE IX-6—SUMMARY OF PRESENT VALUES AND EQUIVALENT ANNUALIZED VALUES FOR THE 2025–2044 TIMEFRAME FOR ESTIMATED MONETIZED COMPLIANCE COSTS, BENEFITS, AND NET BENEFITS FOR THE PROPOSED RULE
[Millions of 2016\$, discounted to 2023]^a

	Health benefits		Climate benefits	Cost ^c		Net benefits	
	3%	7%		3%	7%	3%	7%
2025	\$45 and \$170	\$38 and \$140	\$1.9	\$1.0	\$0.9	\$46 and \$170	\$39 and \$140.
2026	\$44 and \$160	\$35 and \$130	1.9	1.0	0.9	\$45 and \$160	\$36 and \$130.
2027	\$17 and \$94	\$12 and \$72	1.4	3.0	2.6	\$15 and \$92	\$11 and \$71.
2028	\$23 and \$140	\$17 and \$100	1.3	6.6	5.5	\$17 and \$130	\$13 and \$99.
2029	\$22 and \$130	\$16 and \$97	1.3	6.4	5.1	\$17 and \$130	\$12 and \$93.
2030	\$15 and \$89	\$9.9 and \$62	1.4	4.1	3.1	\$12 and \$87	\$8.2 and \$60.
2031	\$15 and \$87	\$9.3 and \$58	1.4	3.9	2.9	\$12 and \$84	\$7.7 and \$56.
2032	\$13 and \$80	\$7.8 and \$51	–0.1	3.8	2.7	\$9.0 and \$76	\$5.0 and \$48.
2033	\$13 and \$78	\$7.3 and \$47	–0.1	3.7	2.5	\$8.8 and \$74	\$4.7 and \$45.
2034	\$12 and \$76	\$6.8 and \$44	–0.1	3.6	2.4	\$8.5 and \$72	\$4.4 and \$42.
2035	\$12 and \$74	\$6.4 and \$41	–0.1	3.5	2.2	\$8.2 and \$70	\$4.1 and \$39.
2036	\$12 and \$71	\$6.0 and \$39	–0.1	3.4	2.1	\$8.0 and \$68	\$3.8 and \$360.
2037	\$11 and \$69	\$5.6 and \$36	–0.1	3.3	1.9	\$7.8 and \$66	\$3.6 and \$34.
2038	\$12 and \$83	\$6.3 and \$43	–0.2	2.9	1.7	\$9.0 and \$80	\$4.4 and \$41.
2039	\$12 and \$81	\$5.9 and \$40	–0.2	2.8	1.5	\$8.7 and \$78	\$4.1 and \$38.
2040	\$11 and \$78	\$5.5 and \$38	–0.2	2.8	1.4	\$8.4 and \$75	\$3.9 and \$36.
2041	\$11 and \$76	\$5.1 and \$35	–0.2	2.7	1.4	\$8.2 and \$73	\$3.6 and \$34.
2042	\$11 and \$74	\$4.8 and \$33	–0.2	2.6	1.3	\$8.0 and \$71	\$3.4 and \$31.

TABLE IX-6—SUMMARY OF PRESENT VALUES AND EQUIVALENT ANNUALIZED VALUES FOR THE 2025–2044 TIMEFRAME FOR ESTIMATED MONETIZED COMPLIANCE COSTS, BENEFITS, AND NET BENEFITS FOR THE PROPOSED RULE—Continued
[Millions of 2016\$, discounted to 2023]^a

	Health benefits		Climate benefits	Cost ^c		Net benefits	
	3%	7%		3%	7%	3%	7%
2043	\$12 and \$79	\$4.8 and \$31	0.0	2.8	1.3	\$8.9 and \$76	\$3.5 and \$30.
2044	\$11 and \$76	\$4.4 and \$29	0.0	2.7	1.2	\$8.6 and \$74	\$3.2 and \$28.
PV 2025–2044	\$330 and \$1,900	\$210 and \$1,200	9.3	67	45	\$270 and \$1,800	\$180 and \$1,100.
EAV 2025–2044	\$22 and \$130	\$20 and \$110	0.6	4.5	4.2	\$18 and \$120	\$17 and \$110.

^a Rows may not appear to add correctly due to rounding.

X. Summary of Proposed Changes to Existing Regulatory Text

This section describes proposed amendments to the regulatory text in the Code of Federal Regulations (CFR) to apply the Federal Good Neighbor Plan's requirements to emissions sources in Arizona, Iowa, Kansas, New Mexico, and Tennessee. The proposed CFR amendments relating to EGUs and to non-EGUs are addressed in section X.A. and section X.B. of this document, respectively. In section X.C. of this document, the EPA describes additional proposed CFR amendments that would make technical corrections or clarifications to the regulatory text as finalized in the Federal Good Neighbor Plan. The EPA has included documents showing the proposed amendments in redline-strikeout format in the docket for this proposed action.

A. Amendments To Apply the Federal Good Neighbor Plan's Requirements to EGUs in Additional States

The primary CFR amendments that would apply the Federal Good Neighbor Plans requirements to EGUs in Arizona, Iowa, Kansas, New Mexico, and Tennessee would be made in the FIP provisions addressing states' good neighbor obligations related to ozone in 40 CFR part 52 as well as in the regulations for the CSAPR NO_x Ozone Season Group 3 Trading Program in 40 CFR part 97, subpart GGGGG. In addition, amendments to address the transition of the EGUs in Iowa, Kansas, and Tennessee from the Group 2 trading program to the Group 3 trading program would be made in the regulations for the Group 2 trading program in 40 CFR part 97, subpart EEEEE, and conforming revisions would be made in the regulations for the Group 1 trading program in 40 CFR part 97, subpart BBBB.

The FIP provisions that identify the states whose EGU sources must participate in the CSAPR NO_x Ozone Season Group 1, Group 2, and Group 3 trading programs with respect to

specified control periods to address transported ozone pollution are set forth at § 52.38(b)(2). The proposed expansion of the applicability of the Group 3 trading program to sources in the five newly added states starting with the 2025 control period would be implemented at § 52.38(b)(2)(iii)(E). The proposed end to the applicability of the Group 2 trading program (with the exception of certain provisions) for sources in Iowa, Kansas, and Tennessee after the 2024 control period would be implemented at § 52.38(b)(2)(ii)(A).

In the Federal Good Neighbor Plan, the EPA retained several previously established options for states to revise their SIPs to modify or replace the FIPs applicable to their sources while continuing to use the Group 3 trading program as the mechanism for meeting the states' good neighbor obligations. Under this proposal, the provision at § 52.38(b)(10) establishing an option for a State to replace allowance allocations for a single control period would be amended to make the option available for the five newly added states for the 2026 control period,¹⁶⁸ with coordinated revisions to the Group 3 trading program regulations as discussed later in this section X.A. The provisions at § 52.38(b)(11) and (12) establishing options for a State to adopt an abbreviated or full SIP revision starting with the 2025 control period would remain available to states already covered by the Group 3 trading program and would be amended to make the options available to the newly added states starting with the 2027 control period.

The general FIP provisions applicable to all states covered by this rule as set forth in § 52.38(b)(2) would be replicated in the state-specific subparts of 40 CFR part 52 for each of the five states that the EPA is proposing to add

to the Group 3 trading program.¹⁶⁹ In each such state-specific CFR subpart, provisions would be added indicating that sources in the State would be required to participate in the CSAPR NO_x Ozone Season Group 3 Trading Program with respect to emissions starting in 2025. Provisions would also be added repeating the substance of § 52.38(b)(13)(i), which provides that the Administrator's full and unconditional approval of a full SIP revision correcting the same SIP deficiency that is the basis for a FIP promulgated in this rulemaking would cause the FIP to no longer apply to sources subject to the State's CAA implementation planning authority, and § 52.38(b)(14)(ii), which provides the EPA with authority to complete recordation of EPA-determined allowance allocations for any control period for which the EPA has already started such recordation notwithstanding the approval of a State's SIP revision establishing state-determined allowance allocations.

For each of the three states that the EPA is proposing to remove from the Group 2 trading program, the provisions of the state-specific CFR subparts indicating that sources in the State are required to participate in that trading program would be revised to end that requirement with respect to emissions after 2024, and a further provision would be added repeating the substance of § 52.38(b)(14)(iii), which identifies certain provisions that continue to apply to sources and allowances notwithstanding discontinuation of a trading program with respect to a particular state. In addition, obsolete text concerning the unexercised option to adopt full SIP revisions to replace the FIPs issued under the CSAPR Update would be removed.

To implement the geographic expansion of the Group 3 trading program and the trading budgets

¹⁶⁸ The provision as it exists before the proposed amendments is obsolete because no State elected to use the provision to establish state-determined allocations for the 2024 control period.

¹⁶⁹ See proposed §§ 52.154(a) (Arizona), 52.840(b) (Iowa), 52.882(b) (Kansas), 52.1641 (New Mexico), and 52.2240(e) (Tennessee).

proposed under the new and amended FIPs in this rulemaking, several sections of the Group 3 trading program regulations would be amended. Revisions identifying the applicable control periods, the starting years for certain allocation provisions, the deadlines for certification of monitoring systems, and the deadlines for commencement of quarterly reporting for sources in the newly added states would be made at §§ 97.1006(c)(3), 97.1012, 97.1030(b)(1), and 97.1034(d)(2)(i), respectively. Revisions identifying the new or revised budgets, new unit set-aside percentages, and variability limits under the Group 3 trading program for the control periods starting in 2025 for the newly added states would be made at § 97.1010, while revisions ending the corresponding provisions under the Group 2 trading program for control periods after 2024 would be made at § 97.810. Revisions to § 97.1021 would establish the schedule for recording unit-level allocations of allowances to sources in the newly added states for the 2025 and 2026 control periods, including the schedule that would apply with respect to allocations for the 2026 control period if a State exercises the proposed option to establish state-determined allocations for that control period.

The proposed creation of an additional Group 3 allowance bank for the 2025 control period through the conversion of banked 2017–2024 Group 2 allowances as discussed in section VII.A.5. of this document would be implemented at a new § 97.826(f)(1).¹⁷⁰ Related provisions addressing the use of Group 3 allowances to satisfy compliance obligations under the Group 1 trading program or the Group 2 trading program arising after the conversion would be implemented at new §§ 97.526(e)(4) and 97.826(g)(3), respectively. Related provisions addressing delayed recordation of allocations of Group 1 or Group 2 allowances after the conversion would be implemented at new §§ 97.526(d)(2)(iv) and 97.826(f)(2), respectively. A coordinating amendment that excludes the emissions budgets of the newly added states from the Group 3 allowance bank recalibration target for the 2025 control period would be implemented at § 97.1026(d)(2).

Finally, the EPA proposes to make conforming revisions to cross-references necessitated by the other amendments already described at § 52.38(b)(14) and

in several sections of the regulations for the Group 1, Group 2, and Group 3 trading programs.

B. Amendments To Apply the Federal Good Neighbor Plan's Requirements to Non-EGUs in Additional States

The CFR amendments that would apply the Federal Good Neighbor Plans requirements to non-EGUs in Arizona would be made in the FIP provisions for non-EGUs promulgated in the Federal Good Neighbor Plan in 40 CFR 52.40 through 52.46. A proposed amendment to § 52.40(c)(2) would extend applicability of the non-EGU requirements under all seven of these CFR sections to Arizona emissions sources starting with the 2027 control period. This provision would be substantively replicated in the state-specific subpart of 40 CFR part 52 for Arizona at proposed § 52.154(b).

In addition, each provision in §§ 52.40 through 52.46 that either repeats the general applicability deadline from § 52.40(c)(2) or that establishes a deadline for a specific requirement or option would be revised to clearly indicate the applicable deadline for sources in Arizona as well as the applicable deadline for sources in states already covered by the Federal Good Neighbor Plan's requirements. In most cases, the EPA is proposing to establish the deadlines for Arizona sources 1 year after the comparable deadlines for sources in the other states. However, in cases where the Federal Good Neighbor Plan established a deadline in terms of a certain interval after the Federal Good Neighbor Plan's effective date, the EPA is proposing to similarly establish a comparable deadline for Arizona sources in terms of the same interval after the effective date of a final rule in this rulemaking.

C. Technical Corrections and Clarifications to Previously Finalized Regulatory Text

In addition to the amendments described in sections X.A. and X.B. for this document to implement the proposed extension of the Federal Good Neighbor Plan's requirements to emissions sources in additional states, the EPA is also proposing to make various technical corrections and clarifications to the previously finalized regulatory text. Most of the revisions would replace incorrect cross-references, improve grammar and clarity, or fix typographical errors. These corrections are not individually described in this preamble but are shown in the documents included in the docket for this rulemaking, which show

all proposed changes to the regulatory text in redline-strikeout format.

Beyond the corrections of cross-references and grammatical and typographical errors, the EPA proposes to make the following additional technical corrections to the regulatory text for EGUs:

- The backstop daily NO_x emissions rate provisions at §§ 97.1006(c)(1)(i)(B) and 97.1024(b)(1)(ii) would be revised to clarify that the 50-ton threshold that must be crossed before cumulative exceedances of the backstop daily rate require surrender of extra allowances applies individually to each unit subject to the backstop rate provisions, as discussed in the Federal Good Neighbor Plan preamble at 88 FR 36791–93, and not to all the units at a source on a collective basis.

- The backstop daily NO_x emissions rate provisions at § 97.1024(b)(3) would be revised to avoid inadvertently applying the backstop emissions rate provisions in control periods after 2029 to units without installed SCR controls in states where the Federal Good Neighbor Plan's identified emissions control stringency does not include the installation of new SCR controls.

- The “maximum controlled baseline” language in the allowance allocation provisions at §§ 97.1011(b)(4)(ii) and 97.1012(a)(4)(ii) would be revised to avoid inadvertently applying SCR-based assumptions in the calculations of allowance allocations to units without installed SCR controls in states where the Federal Good Neighbor Plan's identified emissions control stringency does not include the installation of new SCR controls.

- The secondary emissions limitation provisions at § 97.1025(c)(1) would be revised to clarify that the provisions do not apply before the 2024 control period, as stated in the Federal Good Neighbor Plan preamble at 88 FR 36798 and consistent with the provisions for the timing of compliance requirements at § 97.1006(c)(3)(ii).

- The provisions to create an initial allowance bank for states transitioning to the Group 3 trading program under the Federal Good Neighbor Plan at § 97.826(e)(1)(ii)(B) would be revised to clarify that the initial bank target used to determine the conversion factor is calculated as 21 percent of the sum of the 2024 trading budgets under § 97.1010(a)(1)(i) for the relevant states, not as the potentially different sum of the final 2024 variability limits under § 97.1010(e) for the relevant states, because the final 2024 variability limit values under § 97.1010(e) would not be known until after the deadline for

¹⁷⁰ The provision currently designated as § 97.826(f) would be redesignated as § 97.826(g).

carrying out the bank conversion procedure.

- The provision at § 52.38(b)(14)(iii)(A) that clarifies the continued applicability of the EPA's allowance housekeeping authority after the sources in a State no longer participate in a given trading program would be revised to include Group 3 allowances, in light of the interim transition of sources in several states out of the Group 3 trading program in response to judicial stay orders.

Beyond the corrections of cross-references and grammatical and typographical errors, the EPA proposes to make the following additional technical corrections to the regulatory text for non-EGUs:

- The definition of “ozone season” currently provided as part of the general requirements of the non-EGU regulations at § 52.40(c)(1) would be broken out as a freestanding definition and relocated to § 52.40(b). The revision would clarify the regulations.

- The recordkeeping provisions at §§ 52.41(f), 52.42(e), 52.43(f), 52.44(h)(1) through (3), 52.45(e)(1), and 52.46(f) would be revised by adding language to the introductory text stating that the recordkeeping requirements apply only with respect to operations during the ozone season (unless stated otherwise), consistent with the existing regulations in the general recordkeeping requirements at § 52.40(c)(3). The revisions would also add cross-references to the general recordkeeping requirements at § 52.40(c)(3) and (f), where additional details on recordkeeping requirements are provided. Relatedly, the recordkeeping provisions at § 52.45(e)(2) for low-use industrial boilers would be revised to correctly cross-reference § 52.40(f) (but not § 52.40(c)(3)) and to include language stating that the recordkeeping requirements of that provision apply with respect to operations throughout the calendar year, consistent with the qualification criteria for the low-use exemption. The revisions would clarify the regulations.

- Two types of corrections would be made to the reporting provisions at §§ 52.40(g), 52.41(g), 52.42(f), 52.43(g), 52.44(i), 52.45(f), and 52.46(g). First, a statement would be added to § 52.40(g) clarifying that requirements to use the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) or an analogous electronic submission system provided by the EPA apply with respect to not only annual reports but also excess emissions reports, consistent with similar statements already included in the industry-specific reporting provisions. Second, the

industry-specific reporting provisions for excess emissions reports and annual reports would be revised to remove a statement that the reports are required to be submitted in pdf format, which is not correct in all situations, and to add a statement indicating that the appropriate submission instructions for reports submitted via CEDRI will be provided in CEDRI. In conjunction with the additional cross-reference corrections that the EPA is proposing to make in this rulemaking (as discussed at the beginning of this section X.C.), each of the industry-specific reporting provisions would include a correct cross-reference to the general reporting provisions § 52.40(g), where information on the report format requirements for various situations is set forth in greater detail. The revisions would clarify the regulations.

- Several provisions concerning non-report submissions—that is, optional or required submissions other than required excess emissions reports and annual reports—would be revised to indicate that sources must make the submissions to the EPA via CEDRI or an analogous electronic submission system provided by the EPA. First, provisions at §§ 52.40(e)(1), 52.41(b)(1)(ii), 52.43(d)(4)(iii)(B), and 52.45(d)(2)(vii) which do not currently reflect the EPA's intent for all submissions to be made electronically would be revised to require use of the appropriate standard electronic submission mechanisms. Second, a provision at § 52.43(d)(1) which currently identifies the standard electronic submission mechanisms for reports would be revised to identify the standard electronic submission mechanisms for non-report submissions. Finally, the provision currently designated as § 52.45(d)(4)¹⁷¹ which currently identifies only CEDRI would be revised to also include the standard reference to an analogous electronic submission system. The revisions would make these provisions consistent with the other provisions governing non-report submissions throughout the Federal Good Neighbor Plan's non-EGU regulations and would clarify the regulations. See §§ 52.40(d)(4), (d)(9)(ii), and (e)(7)(ii); 52.41(d); 52.42(g)(2); 52.43(d)(1), (g)(1), and (h)(2); and 52.44(d)(1), (e)(1), and (j)(2).

- In the regulations governing compliance extension requests at § 52.40(d), the regulations governing case-by-case emissions limit requests at § 52.40(e), and the regulations governing steel rehear furnace work plan submissions at § 52.43(d)(4), multiple

revisions would be made to the provisions concerning notifications from the EPA to sources. First, each of the provisions specifically identifying CEDRI as a mechanism for electronic notifications from the EPA would be revised to instead provide for the EPA's notifications to be made more generally “in writing or via an electronic submission system provided by the EPA,” because CEDRI is not currently capable of serving this purpose. Second, a provision at § 52.43(d)(4)(iii)(B) that does not currently identify any electronic notification mechanism would be revised to include the same general reference to “an electronic submission system provided by the EPA” as the other notification provisions. Third, current phrases in §§ 52.40(d)(8) and (e)(6) and 52.43(d)(4)(i) calling for the notifications to be made publicly available would be removed as overly broad, because some of the notifications made under those paragraphs do not concern final Agency decisions but instead concern non-final expressions of intent which the Agency did not mean to include within the scope of the public availability requirements. Finally, the revisions would add a new sentence to § 52.43(d)(4)(ii) that requires the relevant final decisions under that paragraph to be made publicly available but does not require any non-final expressions of intent to be made publicly available. See also § 52.43(d)(4)(iv) (requiring other types of final decisions to be made publicly available). In the case of § 52.40(d)(8) and (e)(6), the removed phrases about public availability requirements would not be replaced because other related provisions already require the relevant final decisions under those paragraphs to be made publicly available. See § 52.40(d)(6) and (e)(4); see also § 52.40(d)(10) and (e)(8) (requiring other types of final decisions to be made publicly available). The revisions would clarify the regulations.

- The definition of “facility” in the regulations for natural gas pipeline engines at § 52.41(a) would be revised to refer to “the set of states” instead of “the 20 states” covered by the non-EGU regulations. The revision would clarify the regulations and maintain the intent of the current definition as finalized in the Federal Good Neighbor Plan, which was to ensure that any facility-wide averaging plans do not extend beyond the geographic area covered by the regulations. See 88 FR 36824.

- The provisions on testing and monitoring requirements for natural gas pipeline engines at § 52.43(e) would be revised to correctly indicate the terms of

¹⁷¹ The EPA is proposing to redesignate this provision as § 52.45(d)(3)(iv).

the partial exemption created for certain engines in the Federal Good Neighbor Plan. As discussed in the rulemaking record, the EPA determined that it is appropriate to exempt engines that operate primarily during peak hours outside the ozone season and that operate for 50 hours or less during the ozone season from most of the testing and monitoring requirements applicable to other engines, with the exception of the requirement for an initial performance test. *See* EPA–HQ–OAR–2021–0668–1127, Federal “Good Neighbor Plan” for the 2015 Ozone National Ambient Air Quality Standards: Response to Public Comments on Proposed Rule, at 657. As revised, the provision at § 52.43(e)(6) would correctly specify which testing and monitoring requirements are covered by the exemption and would state the correct ozone season operating hour ceiling of 50 hours. Also, the largely duplicative provision currently at § 52.43(e)(3)(iii) would be removed and the provision currently designated as § 52.43(e)(3)(iv) would be redesignated as § 52.43(e)(3)(iii). The revisions would bring the regulations into agreement with the EPA’s intent as discussed in the rulemaking record and improve clarity.

- The definitions section of the regulations for cement kilns at § 52.42(a) would be revised by removing a definition of “cement plant” because the term is not used in the final regulations.

- The applicability provisions of the regulations covering steel reheating furnaces at § 52.43(b) would be revised to eliminate the possibility of an incorrect inference that a unit previously affected under the regulations might no longer be affected after installation of low-NO_x burners. The EPA’s intent for the regulations to remain in effect for a given affected unit after any installation of low-NO_x burners is clear from the overall structure of the regulations, including the requirements for work plans to set emissions limits achieving a minimum 40 percent reduction from baseline emissions levels for affected units based on the installation of low-NO_x burners or alternative low-NO_x technologies and the requirements for testing, monitoring, recordkeeping, and reporting to ensure compliance with those limits following installation. *See* § 52.43(d) through (g). There is also no mention anywhere in the regulations or in the preamble of the Federal Good Neighbor Plan of any possibility that a unit’s status could change from affected to non-affected following the installation of low-NO_x

burners. The revision would clarify the regulations.

- The initial notification provisions of the regulations covering steel reheating furnaces at § 52.43(h)(2) would be revised to add a phrase stating that the initial notification requirement does not apply to sources that already have low-NO_x burners installed. The revision would clarify the regulations by making the description of affected units in this paragraph consistent with the applicability criteria set forth in § 52.43(b).

- The emissions limitations provisions for glass manufacturing furnaces at § 52.44(c) would be revised to clarify how and when the exemptions during startup, shutdown and idling apply. As currently written, the provision could be interpreted as allowing an all-or-none package of shutdown and idling exemptions for the 2026 ozone season, if the regulations’ shutdown and idling requirements are all met, and a broader all-or-none package of startup, shutdown, and idling exemptions for subsequent ozone seasons, if the regulations’ startup, shutdown, and idling requirements are all met. The revised language would clarify that the exemptions during startup, shutdown, and idling are each available independently of the other exemptions if the appropriate requirements are met, and that this is the case for all ozone seasons. The EPA’s intent for the startup, shutdown, and idling exemptions to be independent of one another is evident from the Federal Good Neighbor Plan preamble. *See, e.g.,* 88 FR 36831 (“The emissions limits for glass melting furnaces in § 52.44(c) do not apply during periods of start-up, shutdown, and/or idling at affected units that comply instead with the alternative requirements for start-up, shutdown, and/or idling periods specified in § 52.44(d), (e), and/or (f), respectively.” (emphasis added)). Moreover, the preamble contains no discussion indicating any intent for the exemptions to apply differently in the 2026 ozone season than in subsequent ozone seasons. The revisions would clarify the regulations.

- In the recordkeeping provisions for glass manufacturing furnaces at § 52.44(h), a provision concerning operating parameters would be redesignated from § 52.44(h)(1)(vii)(D) to § 52.44(h)(1)(viii) to correctly indicate that the provision’s application is not limited to situations where continuous emissions monitoring systems (CEMS) are being used, and the succeeding subparagraphs of § 52.44(h)(1) would be renumbered accordingly. The correction

is needed because the affected units are required to use the operating parameters for monitoring purposes only when CEMS are not being used. *See* § 52.44(g)(2) and (3).

- The provisions of the industrial boiler testing and monitoring requirements at § 52.45(d)(2)(vii) concerning requests for alternative monitoring requirements would be revised to explicitly require that if such a request is approved, the facility must request that the relevant permitting Agency incorporate the approved monitoring procedure into the facility’s title V permit. The revision would ensure consistency with other provisions of the non-EGU regulations that call for facility-specific requirements to be incorporated into the facility’s title V permits. *See* §§ 52.40(d)(5) and (e)(3) and 52.45(d)(4).¹⁷² The revision would also carry out the Agency’s broader intent expressed in the Federal Good Neighbor Plan for facilities’ applicable requirements to be incorporated into their title V permits. *See* 88 FR 36844.

- The provisions concerning the required annual reports for industrial boilers at § 52.45(f) would be revised to identify the required contents of the reports, which would be the records required under the applicable recordkeeping requirements in § 52.45(e), including records of CEMS data or operating parameters required under § 52.45(d). The required contents of the annual reports for industrial boilers would be fully consistent with the required contents of the annual reports for the other types of non-EGU sources covered by the Federal Good Neighbor Plan. *See* §§ 52.41(g)(3), 52.42(f)(3), 52.43(g)(4), 52.44(i)(3), and 52.46(g)(2). The revision would clarify the regulations by filling an obviously unintended gap, because the regulations currently set forth a requirement for submission of annual reports but lack any description of what the required reports should contain. In addition, because the required contents of the annual reports would include the CEMS-related data that are currently identified as the contents of a separate reporting requirement in § 52.45(f)(3), that separate reporting requirement would be eliminated as redundant, and the annual report provision would be redesignated as § 52.45(f)(3).

- The definitions section of the municipal waste combustor regulations at § 52.46(a) would be revised to include a definition of “municipal solid waste” matching the definition of the same

¹⁷² The EPA is proposing to redesignate § 52.45(d)(4) as § 52.45(d)(3)(iv).

term in the standards of performance for new large municipal waste combustors at 40 CFR 60.51b. The portions of the Federal Good Neighbor Plan preamble discussing the requirements for municipal waste combustors contain no discussion of any intention to introduce a definition of municipal solid waste for these regulations differing from the definition included in the EPA's other regulations for large municipal waste combustors. *See* 88 FR 36836–38. Addition of the definition would clarify the regulations. Also, definitions in § 52.46(a) for “mass burn refractory municipal waste combustor”, “mass burn rotary waterwall municipal waste combustor”, and “mass burn waterwall municipal waste combustor” would be removed because the terms are not used in the final regulation.

- Several provisions of the regulations for municipal waste combustors at § 52.46 would be revised to better implement the EPA's intent concerning the treatment of emissions during periods of startup and shutdown. As indicated in the Final Good Neighbor Plan preamble at 88 FR 36837, the EPA intended to address startup and shutdown emissions following an approach previously adopted in the standards of performance for commercial and industrial solid waste incineration (CISWI) units at 40 CFR part 60, subparts CCCC and DDDD. Under this approach, a single set of emissions limits applies at all times and the calculations of average emissions rates used to determine compliance with the stated emissions limits use the data measured in all operating hours, including periods of startup and shutdown, but unlike the emissions data measured at other times, the emissions data measured during periods of startup and shutdown are not required to be corrected to 7 percent oxygen. *See, e.g.*, 40 CFR 60.2145(j)(2)(i) and (u)(1); 60.2165(n)(4) and (7); 60.2710(j)(2)(i) and (u)(1); and 60.2730(n)(4) and (7). To implement this intended approach in § 52.46, paragraphs (c) and (e)(2)(vi) would be revised to clarify that a single set of 24-hour block average emission limits and 30-day rolling average emissions limits applies at all times, subject to differences in oxygen correction requirements for emissions data measured in periods of startup and shutdown, while paragraphs (d) and (e)(3) would be revised to remove separate emissions limits and monitoring requirements applicable only to periods of startup and shutdown. The revised regulations would implement the EPA's expressed intent concerning the treatment of

emissions during startup and shutdown more accurately than the existing regulations.

- The provisions on testing and monitoring requirements for municipal waste combustors at § 52.46(e)(vi) would be revised to clarify that where a source selects carbon dioxide for use in diluent corrections, the procedures used to determine the relationship between oxygen and carbon dioxide levels would be the procedures set forth for the same purpose in the standards of performance for new large municipal waste combustors at 40 CFR 60.58b(b)(6). This revision would correct an unintended omission and is consistent with the EPA's similar incorporation of aspects of those standards of performance in other provisions of the testing and monitoring requirements for municipal waste combustors at § 52.46(e)(2)(ii) and (3)(i).

- The reporting provisions for municipal waste combustors at § 52.46(g) would be revised to add a provision for excess emissions reports parallel to the excess emissions report provisions for each of the other non-EGU source categories. The EPA expressly indicated the intent to require excess emissions reports from all non-EGU source categories, including municipal waste combustors, in the Federal Good Neighbor Plan preamble. *See* 88 FR 36820. The revision would correct an inadvertent omission and clarify the regulations.

XI. 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 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an economic analysis of the potential impacts associated with this action. This analysis, “Economic Impact Assessment for the Proposed Supplemental Federal “Good Neighbor Plan” Requirements for the 2015 8-hour Ozone National Ambient Air Quality Standard” is briefly summarized in

section IX of this document and is also available in the docket.

B. Paperwork Reduction Act (PRA)

1. Information Collection Request for Electric Generating Units

The information collection activities in this proposed rule have been submitted for approval to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2792.01. The EPA has placed a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The EPA is proposing an ICR, related specifically to EGUs, for this proposal. The proposed rule would amend the CSAPR NO_x Ozone Season Group 3 trading program addressing seasonal NO_x emissions in various states. Under the proposed amendments, all EGU sources located in states covered by the Federal Good Neighbor Plan and unaffected by stay orders would remain in the Group 3 trading program. Additionally, EGU sources in three states (Iowa, Kansas, and Tennessee) currently covered by the CSAPR NO_x Ozone Season Group 2 Trading Program would transition from the Group 2 program to the revised Group 3 trading program beginning with the 2025 ozone season. Further, sources in Arizona and New Mexico not currently covered by any CSAPR NO_x ozone season trading program would join the revised Group 3 trading program. In total, EGU sources in 15 states would now be covered by the Group 3 program.

There is an existing ICR (OMB Control Number 2060–0667), that includes information collection requirements placed on EGU sources for the six Cross-State Air Pollution Rule (CSAPR) trading programs addressing sulfur dioxide (SO₂) emissions, annual NO_x emissions, or seasonal NO_x emissions in various sets of states, and the Texas SO₂ trading program which is modeled after CSAPR. Additionally, the EPA submitted an EGU ICR under the Federal Good Neighbor Plan (OMB Control Number 2060–0745). The ICR in this proposal accounts for the additional respondent burden related to the addition sources in the five states to the CSAPR NO_x Ozone Group 3 trading program.

The principal information collection requirements under the CSAPR and Texas trading programs relate to the monitoring and reporting of emissions and associated data in accordance with 40 CFR part 75. Other information collection requirements under the programs concern the submittal of

information necessary to allocate and transfer emissions allowances and the submittal of certificates of representation and other typically one-time registration forms.

Affected sources under the CSAPR and Texas trading programs are generally stationary, fossil fuel-fired boilers and combustion turbines serving generators larger than 25 MW producing electricity for sale. Most of these affected sources are also subject to the Acid Rain Program (ARP). The information collection requirements under the CSAPR and Texas trading programs and the ARP substantially overlap and are fully integrated. The burden and costs of overlapping requirements are accounted for in the ARP ICR (OMB Control Number 2060–0258). Thus, this ICR accounts for information collection burden and costs under the CSAPR NO_x Ozone Season Group 3 trading program that are incremental to the burden and costs already accounted for in both the ARP and CSAPR ICRs.

For most sources already reporting data under the CSAPR NO_x Ozone Season Group 3 or CSAPR NO_x Ozone Group 2 trading programs, there would be no incremental burden or cost, as reporting requirements will remain identical. Certain sources with a common stack configuration and/or those that are large, coal-fired EGUs, will be subject to additional emissions reporting requirements under the proposed rule. These sources will need to make a one-time monitoring plan and Data Acquisition and Handling System (DAHS) update to meet the additional reporting requirements. There is some incremental cost and burden for those sources in the two states not currently reporting data under a CSAPR NO_x Ozone Season program. Affected sources in Arizona and New Mexico that are already reporting data as part of the Acid Rain Program only require monitoring plan and DAHS updates. For the units that already report to EPA under the Acid Rain Program or the NO_x SIP Call, with the exception of any one-time costs to update monitoring plans and DAHS, all information collection costs and burden are already reflected in the previously approved ICRs for those other rules (OMB Control Nos. 2060–0258 and 2060–0445).

In total, there are an estimated 23 units in Arizona and New Mexico that do not already report data to EPA according to 40 CFR part 75 and that would need to implement one of the Part 75 monitoring methodologies including certification of monitoring systems or implementation of the low mass emissions methodology. These

units would also require monitoring plan and DAHS updates. Of these 23 units, nine units would be expected to adopt low mass emissions (LME) as the monitoring method and 14 would be expected to adopt NO_x CEMS/Appendix D monitoring methods.

Respondents/affected entities:

Industry respondents are stationary, fossil fuel-fired boilers and combustion turbines serving electricity generators subject to the CSAPR and Texas trading programs, as well as non-source entities voluntarily participating in allowance trading activities. Potential State respondents are states that can elect to submit state-determined allowance allocations for sources located in their states.

Respondent's obligation to respond:

Industry respondents: voluntary and mandatory (sections 110(a) and 301(a) of the CAA).

Estimated number of respondents:

EPA estimates that there would be 64 industry respondents.

Frequency of response: on occasion, quarterly, and annually.

Total estimated additional burden:

7,538 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated additional cost:

\$1,243,126 (per year); includes \$593,874 annualized capital or operation and 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.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than March 18, 2024. The EPA will respond to any ICR-related comments in the final rule.

2. Information Collection Request for Non-Electric Generating Units

The information collection activities in this proposed rule are included within OMB ICR Number 2060–0744, ICR for the Final Rule, Federal “Good Neighbor Plan” for the 2015 Ozone National Ambient Air Quality

Standards: Transport Obligations for non-Electric Generating Units. The EPA submitted this ICR to OMB under the PRA during the development of the Federal Good Neighbor Plan. In this action, the EPA proposes to extend the non-EGU regulatory requirements to affected units within the State of Arizona under the same rationale provided in the Federal Good Neighbor Plan. Because the respondent pool in this action is not well-defined and because the number of affected non-EGU sources in Arizona estimated to install controls is fewer than ten, we are not proposing to develop a new ICR or revise the existing ICR at this time. We will, however, revise the ICR to include any covered non-EGU sources in Arizona when we renew the ICR. The EPA has filed a copy of the non-EGU ICR in the docket for this rule, and it is briefly summarized here.

ICR No. 2060–0744 is an existing ICR that addresses the burden associated with new regulatory requirements under the Federal Good Neighbor Plan. Owners and operators of certain non-EGU industry stationary sources will potentially modify or install new emissions controls and associated monitoring systems to meet the NO_x emissions limits of this final rule. The burden in ICR 2060–0744 reflects the new monitoring, calibrating, recordkeeping, reporting and testing activities required of covered industrial sources, which we are collecting to ensure compliance with the Federal Good Neighbor Plan. In accordance with the CAA Amendments of 1990, any monitoring information to be submitted by sources is a matter of public record. Information received and identified by owners or operators as CBI and approved as CBI by the EPA, in accordance with Title 40, Chapter 1, part 2, subpart B, shall be maintained appropriately (*see* 40 CFR part 2; 41 FR 36902, September 1, 1976; amended by 43 FR 39999, September 8, 1978; 43 FR 42251, September 28, 1978; 44 FR 17674, March 23, 1979).

Respondents/affected entities: The respondents/affected entities are the owners/operators of certain non-EGU industry sources in the following industry sectors: furnaces in Glass and Glass Product Manufacturing; boilers and furnaces in Iron and Steel Mills and Ferroalloy Manufacturing; kilns in Cement and Cement Product Manufacturing; reciprocating internal combustion engines in Pipeline Transportation of Natural Gas; and boilers in Metal Ore Mining, Basic Chemical Manufacturing, Petroleum and Coal Products Manufacturing, and Pulp, Paper, and Paperboard Mills; and

combustors and incinerators in Solid Waste Combustors and Incinerators.

Respondent's obligation to respond: Voluntary and mandatory. (Sections 110(a) and 301(a) of the CAA). Data recorded or reported by respondents are required by the final Federal Good Neighbor Plan.

Estimated number of respondents: 3,328.

Frequency of response: The specific frequency for each information collection activity within the non-EGU ICR is shown at the end of the ICR document in Tables 1 through 18. In general, the frequency varies across the monitoring, recordkeeping, and reporting activities. Some recordkeeping such as work plan preparation is a one-time activity whereas pipeline engine maintenance recordkeeping is conducted quarterly. Reporting frequency is on an annual basis.

Total estimated burden: 11,481 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$3,823,000 (average per year); includes \$2,400,000 annualized capital or operation and maintenance costs.

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 small businesses, which includes EGUs and non-EGUs and are briefly described below. In 2028, the EPA identified a total of four EGUs owned by small entities affected by the proposed rule. Of these, no small entities are estimated to have costs greater than 1 percent of revenues.

The Agency has determined that there is not a significant number of small entities potentially affected by the proposed rule that will have compliance costs greater than 1 percent of annual revenues during the compliance period. The EPA has concluded that there is not a significant economic impact on a substantial number of small entities for this proposed rule overall. Details of this analysis are presented in section 3 of the EIA, which is in the public docket.

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. This action imposes no enforceable duty on any State, local or Tribal government. The action imposes no enforceable duty

on any state, local or tribal governments or the private sector.

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.

The EPA is proposing a finding that interstate transport of ozone precursor emissions from five upwind states (Arizona, Iowa, Kansas, New Mexico, and Tennessee) is interfering with maintenance of the 2015 ozone NAAQS in other states. The EPA is proposing FIP requirements to eliminate interstate transport of ozone precursors from these five states. Under CAA section 301(d)(4), the EPA is proposing to extend FIP requirements to apply in Indian country located within the upwind geography of the final rule, including Indian reservation lands and other areas of Indian country over which the EPA or a tribe has demonstrated that a tribe has jurisdiction. The EPA's proposed determinations in this regard are described further in section V.B., *Application of Rule in Indian Country and Necessary or Appropriate Finding*. The EPA proposes that all covered existing and new EGU and non-EGU sources that are located in the "301(d) FIP" areas within the geographic boundaries of the covered states, and which would be subject to this rule if located within areas subject to State CAA planning authority, should be included in this rule. To the EPA's knowledge, two covered existing EGU or non-EGU sources are located within the 301(d) FIP areas: the South Point Energy Center located on the Fort Mojave Reservation, and the Four Corners Power Plant on the Navajo Reservation. These EGU sources are geographically located within the borders of Arizona and New Mexico, respectively. This action has Tribal implication because of the extension of FIP requirements into Indian country and because, in general, tribes have a vested interest in how this final rule would affect air quality.

The EPA consulted with Tribal officials under the EPA Policy on

Consultation and Coordination with Indian Tribes early in the process of developing the Federal Good Neighbor Plan to permit them to have meaningful and timely input into its development. The EPA hosted an environmental justice webinar on October 26, 2021, that was attended by State regulatory authorities, environmental groups, federally recognized tribes, and small business stakeholders. Summaries of prior consultations are included in the docket for the Federal Good Neighbor Plan (Docket ID No. EPA-HQ-OAR-2021-0668). The EPA will also continue to consult with the governments of the Fort Mojave Indian Tribe of the Fort Mojave Reservation, the Navajo Nation of the Navajo Reservation, and plans to further consult with any other Tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this proposed regulation to solicit meaningful and timely input into its development. The EPA plans to issue Tribal consultation letters addressed to the appropriate tribes in [Month Year] after the proposed rule is signed. Consultation summaries will be included in the docket for this action and in a summary section in the preamble when this action is finalized.

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

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in Chapters 3 and 4 of the *Economic Impact Assessment for the Proposed Supplemental Federal "Good Neighbor Plan" Requirements for the 2015 8-hour Ozone National Ambient Air Quality Standard*. The EPA determined that the ozone-related benefits, Fine Particulate Matter-related benefits, and CO₂-related benefits from this final rule will further improve children's health.

However, the EPA's Policy on Children's Health applies to this action. Information on how the Policy was applied is available in the *Economic Impact Assessment for the Proposed*

Supplemental Federal “Good Neighbor Plan” Requirements for the 2015 8-hour Ozone National Ambient Air Quality Standard.

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. The EPA has prepared a Statement of Energy Effects for the proposed regulatory control alternative as follows. The Agency estimates a 0 percent change in retail electricity prices on average across the contiguous U.S. in 2025 and a 0 percent change in retail electricity prices on average across the contiguous U.S. in 2028 as a result of this proposed rule. Additional details of the estimated retail electricity price changes are presented in section 3 of the *EIA at proposal*, which is in the public docket.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

The EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on communities with environmental justice concerns. The documentation for this decision is contained in section VIII, *Environmental Justice Considerations, Implications, and Outreach* of this Preamble. Briefly, proximity demographic analyses found larger percentages of Hispanics, people below the poverty level, people with less educational attainment, and people linguistically isolated are living within 5 km and 10 km of an affected EGU, compared to national averages. It also finds larger percentages of Native Americans and people below the poverty level living within 5 km and 10 km of an affected non-EGU facility.

The EPA believes that this action is not likely to result in new disproportionate and adverse effects on communities with environmental justice concerns. Importantly, the action described in this rule is expected to lower ozone and PM_{2.5} in some areas,

including in ozone nonattainment areas, and thus mitigate some pre-existing health risks across most populations and communities evaluated.

K. Determinations Under CAA Section 307(b)(1) and (d)

Section 307(b)(1) of the CAA governs judicial review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the D.C. Circuit: (1) when the Agency action consists of “nationally applicable regulations promulgated, or final actions taken, by the Administrator,” or (2) when such action is locally or regionally applicable, if “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.” For locally or regionally applicable final actions, the CAA reserves to the EPA complete discretion to decide whether to invoke the exception in (2).¹⁷³

The EPA anticipates that this proposed rulemaking, if finalized, would be “nationally applicable” within the meaning of CAA section 307(b)(1) because it would extend the applicability of the Federal Good Neighbor Plan promulgated on March 15, 2023 (88 FR 36654 (June 5, 2023)), which as promulgated would apply to 23 states across the nation, to five additional states located in four EPA regions and four Federal judicial circuits, in conjunction with partial disapproval of the SIP submissions from these five states. The final rule would directly implement the Federal Good Neighbor Plan in these five additional states based on application of the same, nationally consistent 4-step interstate transport framework for assessing good neighbor obligations for the 2015 ozone NAAQS that the EPA applied in the Federal Good Neighbor Plan promulgated on March 15, 2023, and in other nationally applicable rulemakings, such as CSAPR, the CSAPR Update, and the Revised CSAPR Update. The final rule would thus apply a uniform, nationwide analytical method and interpretation of CAA section 110(a)(2)(D)(i)(I) across the covered states, expanding the scope of the Federal Good Neighbor Plan to a total of up to 28 states across the nation. The

final rule would also make technical corrections to the nationally applicable regulatory provisions promulgated in the Federal Good Neighbor Plan, *see* section X.C. of this document.

In the alternative, to the extent a court finds this action, if finalized, to be locally or regionally applicable, the Administrator intends to exercise the complete discretion afforded to him under the CAA to make and publish a finding that the final action is based on several determinations of “nationwide scope or effect” within the meaning of CAA section 307(b)(1). This proposal, if finalized, would be based on several determinations of nationwide scope or effect, each of which has the purpose of ensuring consistency and equity across all states, including: (1) the determination that use of the same 2023 and 2026 analytical year air quality modeling and monitoring analytics (including the use of the violating-monitor receptor identification methodology) that were used to define all other states’ good neighbor obligations for the 2015 ozone NAAQS is appropriate for purposes of defining the obligations of the five additional states in this action; (2) the determination that use of a 1 percent of NAAQS threshold is appropriate for all states at Step 2 and that neither reliance on the EPA’s August 2018 1 ppb Memo standing alone nor reliance on EPA’s guidance on “significant impact levels” (SIL) for the prevention of significant deterioration (PSD) permitting program provides adequate justification for an alternative threshold; (3) the determination that the same level of emissions control stringency to the same industry and source types at Step 3 as was determined for 23 other states in the Federal Good Neighbor Plan is appropriate to apply to these five additional states; and (4) the determination that the relevant sources in these five states should be subject to the same nationally uniform emissions control programs promulgated at Step 4 for 23 other states in the Federal Good Neighbor Plan.¹⁷⁴

These determinations would provide important bases for the action, if finalized, are needed to ensure consistency and equity in the treatment of all states in addressing the multistate problem of interstate ozone pollution

¹⁷³ In deciding whether to invoke the exception by making and publishing a finding that an action is based on a determination of nationwide scope or effect, the Administrator takes into account a number of policy considerations, including his judgment balancing the benefit of obtaining the D.C. Circuit’s authoritative centralized review versus allowing development of the issue in other contexts and the best use of Agency resources.

¹⁷⁴ A finding of nationwide scope or effect is also appropriate for actions that cover states in multiple judicial circuits. In the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator’s determination that the “nationwide scope or effect” exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. *See* H.R. Rep. No. 95–294 at 323, 324, reprinted in 1977 U.S.C.C.A.N. 1402–03.

under the good neighbor provision for the 2015 ozone NAAQS, and are not related to the particularities of the emissions sources in any specific state. The Federal Good Neighbor Plan and related rulemakings such as this one are designed as a “collective approach” to effectively address the nationwide problem of interstate ozone transport in an equitable and consistent manner across all states. *See Kentucky Energy and Environment Cabinet v. EPA*, No. 23–3605 (6th Cir. Nov. 9, 2023), Order at 8. The determinations underlying this proposed action are therefore of nationwide scope and effect, among other reasons, because they ensure that the requirements of the Federal Good Neighbor Plan (until replaced by SIPs meeting the statutory requirements) will be implemented on a consistent basis across all “upwind” states, and will deliver the full amount of relief from upwind emissions that the EPA has found downwind jurisdictions are due.¹⁷⁵ For these reasons, the Administrator intends, if this proposed action is finalized, to exercise the complete discretion afforded to him under the CAA to make and publish a finding that this action is based on several determinations of nationwide scope or effect for purposes of CAA section 307(b)(1), including, but not limited to, those identified above.

This action is subject to the provisions of CAA section 307(d). CAA section 307(d)(1)(B) provides that section 307(d) applies to, among other things, “the promulgation or revision of an implementation plan by the Administrator under [CAA section 110(c)].” 42 U.S.C. 7407(d)(1)(B). This proposed action, among other things, proposes Federal implementation plans for five additional states to extend the coverage of the Federal Good Neighbor Plan promulgated at 88 FR 36654 (June 5, 2023). To the extent any portion of this action is not expressly identified under CAA section 307(d)(1)(B), the Administrator determines that the provisions of CAA section 307(d) apply to such action. *See* CAA section 307(d)(1)(V) (the provisions of section 307(d) apply to “such other actions as the Administrator may determine”).

¹⁷⁵ In the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator’s determination that the “nationwide scope or effect” exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. *See* H.R. Rep. No. 95–294 at 323, 324, reprinted in 1977 U.S.C.C.A.N. 1402–03.

List of Subjects

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Sulfur dioxide.

40 CFR Part 97

Environmental protection, Administrative practice and procedure, Air pollution control, Electric power plants, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Michael Regan,
Administrator.

For the reasons stated in the preamble, parts 52 and 97 of title 40 of the Code of Federal Regulations are proposed to be 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 A—General Provisions

- 2. Amend § 52.38 by:
- a. In paragraphs (a)(4)(i)(C) and (a)(5)(i)(C), removing “following the control” and adding in its place “following the year of such control”;
 - b. In paragraph (b)(2)(ii)(A), removing “2017 and each subsequent year” and adding in its place “2017 through 2024 only, except as provided in paragraph (b)(14)(iii) of this section”;
 - c. Adding paragraph (b)(2)(iii)(E);
 - d. In paragraphs (b)(4)(ii)(C), (b)(5)(ii)(C), (b)(8)(iii)(C), and (b)(9)(iii)(C), removing “following the control” and adding in its place “following the year of such control”;
 - e. Revising paragraph (b)(10) introductory text;
 - f. In paragraph (b)(10)(ii), removing “2024, of” and adding in its place “2026, of”;
 - g. Revising paragraphs (b)(10)(v)(A) and (B);
 - h. In paragraph (b)(11)(iii) introductory text and paragraph (b)(12)(iii) introductory text, removing “2025 or” and adding in its place “2025 (or for a State listed in paragraph (b)(2)(iii)(E) of this section, 2027) or”;
 - i. In paragraph (b)(14)(i)(G), removing “§ 97.826(f)” and adding in its place “§ 97.826(g)”;
 - j. In paragraph (b)(14)(iii) introductory text, removing “paragraphs (b)(2)(i)(B),

(b)(2)(ii)(B) or (C), (b)(2)(iii)(D)(1), or” and adding in its place “paragraph (b)(2) or”;

■ k. Revising paragraph (b)(14)(iii)(A);

■ l. In paragraph (b)(14)(iii)(B), removing “97.826(d) and (e), and” and adding in its place “97.826(d) through (f), and”;

■ m. In paragraph (b)(17)(i), removing “2024” and adding in its place “2026”.

The addition and revisions read as follows:

§ 52.38 What are the requirements of the Federal Implementation Plans (FIPs) for the Cross-State Air Pollution Rule (CSAPR) relating to emissions of nitrogen oxides?

* * * * *

(b) * * *

(2) * * *

(iii) * * *

(E) The provisions of subpart GGGGG of part 97 of this chapter apply to sources in each of the following States and Indian country located within the borders of such States with regard to emissions occurring in 2025 and each subsequent year: Arizona, Iowa, Kansas, New Mexico, and Tennessee.

* * * * *

(10) *State-determined allocations of CSAPR NO_x Ozone Season Group 3 allowances for 2026.* A State listed in paragraph (b)(2)(iii)(E) of this section may adopt and include in a SIP revision, and the Administrator will approve, as CSAPR NO_x Ozone Season Group 3 allowance allocation provisions replacing the provisions in § 97.1011(a)(1) of this chapter with regard to sources in the State and areas of Indian country within the borders of the State subject to the State’s SIP authority for the control period in 2026, a list of CSAPR NO_x Ozone Season Group 3 units and the amount of CSAPR NO_x Ozone Season Group 3 allowances allocated to each unit on such list, provided that the list of units and allocations meets the following requirements:

* * * * *

(v) * * *

(A) By [15 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], the State must notify the Administrator electronically in a format specified by the Administrator of the State’s intent to submit to the Administrator a complete SIP revision meeting the requirements of paragraphs (b)(10)(i) through (iv) of this section by April 1, 2025; and

(B) The State must submit to the Administrator a complete SIP revision described in paragraph (b)(10)(v)(A) of this section by April 1, 2025.

* * * * *

(14) * * *

(iii) * * *

(A) The provisions of §§ 97.526(c), 97.826(c), and 97.1026(c) of this chapter (concerning the transfer of CSAPR NO_x Ozone Season Group 1 allowances, CSAPR NO_x Ozone Season Group 2 allowances, and CSAPR NO_x Ozone Season Group 3 allowances between certain Allowance Management System accounts under common control);

* * * * *

§ 52.39 [Amended]

- 3. Amend § 52.39 in paragraphs (e)(1)(iii), (f)(1)(iii), (h)(1)(iii), and (i)(1)(iii) by removing “following the control” and adding in its place “following the year of such control”.
- 4. Amend § 52.40 by:
 - a. In paragraph (a), removing “paragraph (b)” and adding in its place “paragraph (c)(1)”;
 - b. In paragraph (b):
 - i. In the introductory text, removing the section symbol before “52.46”;
 - ii. Revising the definitions “Existing affected unit” and “New affected unit”; and
 - iii. Adding the definition “Ozone season” in alphabetical order;
 - c. In paragraph (c)(1), removing “(defined as May 1 through September 30 of a calendar year)”;
 - d. Redesignating paragraph (c)(2) as paragraph (c)(2)(i) and adding paragraph (c)(2)(ii);
 - e. Revising paragraph (d)(1);
 - f. In paragraph (d)(2), removing “May 1, 2029” and adding in its place “the start date of the fourth ozone season identified for the applicable State in § 52.40(c)(2)”;
 - g. Revising paragraphs (d)(3)(v) and (d)(4) through (8) and paragraph (d)(9) introductory text;
 - h. In paragraph (d)(9)(ii), removing “the CEDRI or” and adding in its place “CEDRI or an”;
 - i. Revising paragraphs (d)(10) and (11) and (e)(1);
 - j. In paragraph (e)(2)(i)(A)(1), removing “63.7(e)(2)(ii)(2), or” and adding in its place “63.7(e)(2)(ii), or”;
 - k. Revising paragraphs (e)(3) through (6) and paragraph (e)(7) introductory text;
 - l. In paragraph (e)(7)(ii), removing “the CEDRI or” and adding in its place “CEDRI or an”;
 - m. Revising paragraph (e)(8);
 - n. In paragraph (g)(1)(i), removing “the CEDRI or” and adding in its place “CEDRI or an”; and
 - o. Revising paragraphs (g)(1)(iii)(D) and (g)(2).

The revisions and additions read as follows:

§ 52.40 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from sources not subject to the CSAPR ozone season trading program?

* * * * *

(b) * * *

Existing affected unit means any affected unit for which construction commenced before August 4, 2023, for a unit in a State listed in paragraph (c)(2)(i) of this section, or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in paragraph (c)(2)(ii) of this section.

New affected unit means any affected unit for which construction commenced on or after August 4, 2023, for a unit in a State listed in paragraph (c)(2)(i) of this section, or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in paragraph (c)(2)(ii) of this section.

* * * * *

Ozone season means the period between May 1 and September 30, inclusive, for a given year.

* * * * *

(c) * * *

(ii) The provisions of this section or § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46 apply to affected units located in each of the following States, including Indian country located within the borders of such States, beginning in the 2027 ozone season and in each subsequent ozone season: Arizona.

* * * * *

(d) * * *

(1) The owner or operator of an existing affected unit under § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46 that cannot comply with the applicable requirements in those sections by the start date of the first ozone season identified for the applicable State in paragraph (c)(2) of this section, due to circumstances entirely beyond the owner or operator's control, may request an initial compliance extension to a date certain no later than the start date of the second ozone season identified for the applicable State in paragraph (c)(2) of this section. The extension request must contain a demonstration of necessity consistent with the requirements of paragraph (d)(3) of this section.

* * * * *

(3) * * *

(v) Identify the owner or operator's proposed compliance date. A request for an initial compliance extension under paragraph (d)(1) of this section must specify a proposed compliance date no later than the start date of the second ozone season identified for the applicable State in paragraph (c)(2) of this section and state whether the owner

or operator anticipates a need to request a second compliance extension. A request for a second compliance extension under paragraph (d)(2) of this section must specify a proposed compliance date no later than the start date of the fourth ozone season identified for the applicable State in paragraph (c)(2) of this section and identify additional actions taken by the owner or operator to ensure that the affected unit(s) will be in compliance with the applicable requirements in this section by that proposed compliance date;

* * * * *

(4) Each request for a compliance extension shall be submitted via the Compliance and Emissions Data Reporting Interface (CEDRI) or an analogous electronic submission system provided by the EPA no later than 180 days prior to the applicable compliance date. Until an extension has been granted by the Administrator under this section, the owner or operator of an affected unit shall comply with all applicable requirements of this section and shall remain subject to the compliance date under paragraph (c)(2) of this section or the initial extended compliance date under paragraph (d)(1) of this section, as applicable. A denial will be effective as of the date of denial.

(5) The owner or operator of an affected unit who has requested a compliance extension under paragraph (d)(1) or (2) of this section and is required to have a title V permit shall apply to have the relevant title V permit revised to incorporate the conditions of the extension of compliance. The conditions of a compliance extension granted under paragraph (d)(6) of this section will be incorporated into the affected unit's title V permit according to the provisions of an EPA-approved state operating permit program or the Federal title V regulations in 40 CFR part 71, whichever apply.

(6) Based on the information provided in any request made under paragraph (d)(1) or (2) of this section or other information, the Administrator may grant an extension of time to comply with applicable requirements in § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46 consistent with the provisions of paragraph (d)(1) or (2). The decision to grant an extension will be provided by notification in writing or via an electronic submission system provided by the EPA, will be made publicly available, and will identify each affected unit covered by the extension; specify the termination date of the extension; and specify any additional conditions that the Administrator deems necessary

to ensure timely installation of the necessary controls (*e.g.*, the date(s) by which on-site construction, installation of control equipment, and/or process changes will be initiated).

(7) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of an affected unit who has requested a compliance extension under paragraph (d)(1) or (2) of this section whether the submitted request is complete, that is, whether the request contains sufficient information to make a determination, within 60 calendar days after receipt of the original request and within 60 calendar days after receipt of any supplementary information.

(8) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of a decision to grant or intention to deny a request for a compliance extension within 60 calendar days after providing written notification pursuant to paragraph (d)(7) of this section that the submitted request is complete.

(9) Before denying any request for an extension of compliance, the Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of the Administrator's intention to issue the denial, together with:

* * * * *

(10) The Administrator's final decision to deny any request for an extension will be provided in writing or via an electronic submission system provided by the EPA, will be made publicly available, and will set forth the specific grounds on which the denial is based. The final decision will be made within 60 calendar days after presentation of additional information or argument (if the request is complete), or within 60 calendar days after the deadline for the submission of additional information or argument under paragraph (d)(9)(ii) of this section, if no such submission is made.

(11) The granting of an extension under this section shall not abrogate the Administrator's authority under section 114 of the Act.

(e) * * *

(1) The owner or operator of an existing affected unit under § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46 that cannot comply with the applicable requirements in those sections due to technical impossibility or extreme economic hardship may submit to the Administrator, by August 5, 2024, for a unit in a State listed in

paragraph (c)(2)(i) of this section, or [ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in paragraph (c)(2)(ii) of this section, a request for approval of a case-by-case emissions limit. The request must be submitted via CEDRI or an analogous electronic submission system provided by the EPA and shall contain information sufficient for the Administrator to confirm that the affected unit is unable to comply with the applicable emissions limit, due to technical impossibility or extreme economic hardship, and to establish an appropriate alternative case-by-case emissions limit for the affected unit. Until a case-by-case emissions limit has been approved by the Administrator under this section, the owner or operator shall remain subject to all applicable requirements in § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46. A denial will be effective as of the date of denial.

* * * * *

(3) The owner or operator of an affected unit who has requested a case-by-case emissions limit under paragraph (e)(1) of this section and is required to have a title V permit shall apply to have the relevant title V permit revised to incorporate the case-by-case emissions limit. Any case-by-case emissions limit approved under paragraph (e)(4) of this section will be incorporated into the affected unit's title V permit according to the provisions of an EPA-approved state operating permit program or the Federal title V regulations in 40 CFR part 71, whichever apply.

(4) Based on the information provided in any request made under paragraph (e)(1) of this section or other information, the Administrator may approve a case-by-case emissions limit that will apply to an affected unit in lieu of the applicable emissions limit in § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46. The decision to approve a case-by-case emissions limit will be provided in writing or via an electronic submission system provided by the EPA, will be made publicly available, and will identify each affected unit covered by the case-by-case emissions limit.

(5) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of an affected unit who has requested a case-by-case emissions limit under paragraph (e)(1) of this section whether the submitted request is complete, that is, whether the request contains sufficient information to make a determination, within 60 calendar days

after receipt of the original request and within 60 calendar days after receipt of any supplementary information.

(6) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of a decision to approve or intention to deny the request for a case-by-case emissions limit within 60 calendar days after providing notification pursuant to paragraph (e)(5) of this section that the submitted request is complete.

(7) Before denying any request for a case-by-case emissions limit, the Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of the Administrator's intention to issue the denial, together with:

* * * * *

(8) The Administrator's final decision to deny any request for a case-by-case emissions limit will be provided by notification in writing or via an electronic submission system provided by the EPA, will be made publicly available, and will set forth the specific grounds on which the denial is based. The final decision will be made within 60 calendar days after presentation of additional information or argument (if the request is complete), or within 60 calendar days after the deadline for the submission of additional information or argument under paragraph (e)(7)(ii) of this section, if no such submission is made.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(D) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the Office of Air Quality Planning and Standards (OAQPS) CBI Office at the email address oaqpscbi@epa.gov, should include clear CBI markings as described in paragraph (g)(1)(iii)(C) of this section, and should be flagged to the attention of Lead of 2015 Ozone Transport FIP. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email oaqpscbi@epa.gov to request a file transfer link.

* * * * *

(2) Annual reports and excess emissions reports must be submitted via CEDRI or an analogous electronic reporting approach provided by the EPA

to report data required by § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46.

* * * *

■ 5. Amend § 52.41 by:

■ a. In paragraph (a):

■ i. In the definition for “Cap”, removing “sum each” and adding in its place “sum of each”;

■ ii. In the definition for “Facility”, removing “20 states identified in § 52.40(b)(2)” and adding in its place “set of states identified in § 52.40(c)”;

■ iii. In the definition for “Rich burn”, removing “affected unit where” and adding in its place “affected units where”;

■ b. Revising paragraph (b)(1) introductory text, paragraph (b)(1)(ii), and paragraph (c) introductory text;

■ c. In paragraph (d) introductory text, removing “the CEDRI or” and adding in its place “CEDRI or an”;

■ d. Redesignating the second paragraph (d)(1)(iv) as paragraph (d)(1)(v);

■ e. In paragraph (d)(4), removing “an affected units” and adding in its place “an affected unit”;

■ f. Removing paragraph (e)(3)(iii) and redesignating paragraph (e)(3)(iv) as paragraph (e)(3)(iii);

■ g. In paragraph (e)(5) introductory text, removing “owner of operator” and adding in its place “owner or operator”;

■ h. Revising paragraph (e)(6) and paragraph (f) introductory text;

■ i. In paragraph (f)(1), removing “paragraph (e)(2)” and adding in its place “paragraph (e)(3)”;

■ j. In paragraph (f)(2), removing “paragraph (e)(3)” and adding in its place “paragraph (e)(4)”;

■ k. Revising paragraphs (g)(1) and (2), paragraph (g)(3) introductory text, and paragraph (g)(3)(i).

The revisions read as follows:

§ 52.41 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from the Pipeline Transportation of Natural Gas Industry?

* * * *

(b) * * *

(1) For purposes of this section, the owner or operator of an emergency stationary RICE must operate the RICE according to the requirements in paragraphs (b)(1)(i) through (iii) of this section to be treated as an emergency stationary RICE. In order for a stationary RICE to be treated as an emergency RICE under this section, any operation other than emergency operation, maintenance and testing, and operation in non-emergency situations for up to 50 hours per year, as described in paragraphs (b)(1)(i) through (iii), is prohibited. If

you do not operate the RICE according to the requirements in paragraphs (b)(1)(i) through (iii), the RICE will not be considered an emergency engine under this section and must meet all requirements for affected units in this section.

* * * *

(ii) The owner or operator may operate an emergency stationary RICE for maintenance checks and readiness testing for a maximum of 100 hours per calendar year, provided that the tests are recommended by a Federal, state, or local government agency, the manufacturer, the vendor, or the insurance company associated with the engine. Any operation for non-emergency situations as allowed by paragraph (b)(1)(iii) of this section counts as part of the 100 hours per calendar year allowed by this paragraph (b)(1)(ii). The owner or operator may petition the Administrator for approval of additional hours to be used for maintenance checks and readiness testing, but a petition is not required if the owner or operator maintains records confirming that Federal, state, or local standards require maintenance and testing of emergency RICE beyond 100 hours per calendar year. Any petition must be submitted via CEDRI or an analogous electronic submission system provided by the EPA. Any approval of a petition for additional hours granted by the Administrator under 40 CFR part 63, subpart ZZZZ, shall constitute approval by the Administrator of the same petition under this paragraph (b)(1)(ii).

* * * *

(c) *Emissions limitations.* If you are the owner or operator of an affected unit, you must meet the following emissions limitations on a 30-day rolling average basis during each ozone season identified for the applicable State in § 52.40(c)(2):

* * * *

(e) * * *

(6) If you are the owner or operator of an affected unit that is only operated during peak periods outside of the ozone season and your hours of operation during the ozone season are 50 or less, you are not subject to the testing and monitoring requirements of paragraphs (e)(4) and (5) of this section as long as you record and report your hours of operation during the ozone season in accordance with paragraphs (f) and (g) of this section.

(f) *Recordkeeping requirements.* If you are the owner or operator of an affected unit, you shall maintain records of the following information for each day the affected unit operates during the ozone

season consistent with the requirements of § 52.40(c)(3) and (f):

* * * *

(g) * * *

(1) If you are the owner or operator of an affected unit, you must submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(2) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that occurred during the reporting period. Excess emissions are defined as any calculated 30-day rolling average NO_x emissions rate that exceeds the applicable emissions limit in paragraph (c) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(3) If you are the owner or operator of an affected unit, you must submit an annual report to the EPA by January 30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall contain the following information:

(i) The name and address of the owner or operator;

* * * *

■ 6. Amend § 52.42 by:

■ a. In paragraph (a), removing the definition “Cement plant”;

■ b. Revising paragraph (b) and paragraph (c) introductory text;

■ c. In equation 1 to paragraph (d)(1):

■ i. In the definition for “P”, removing “Time” and adding in its place “time”;

■ ii. In the definition for “n”, removing “n = Number” and adding in its place “N = Number”;

■ d. In paragraph (d)(3) introductory text, removing “2026 ozone season” and adding in its place “start date of the first ozone season identified for the applicable State in § 52.40(c)(2)”;

■ e. In paragraph (d)(3)(v), removing “paragraph (e)” and adding in its place “paragraph (f)”;

■ f. Revising paragraph (e) introductory text, paragraphs (f)(1) through (3), and paragraph (g)(2) introductory text.

The revisions read as follows:

§ 52.42 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from the Cement and Concrete Product Manufacturing Industry?

* * * * *

(b) *Applicability.* You are subject to the requirements of this section if you own or operate a new or existing cement kiln that is located within any of the States listed in § 52.40(c)(2), including Indian country located within the borders of any such State(s), and emits or has the potential to emit 100 tons per year or more of NO_x on or after August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). Any existing cement kiln with a potential to emit of 100 tons per year or more of NO_x on the date specified for the unit in the preceding sentence will continue to be subject to the requirements of this section even if that unit later becomes subject to a physical or operational limitation that lowers its potential to emit below 100 tons per year of NO_x.

(c) *Emissions limitations.* If you are the owner or operator of an affected unit, you must meet the following emissions limitations on a 30-day rolling average basis during each ozone season identified for the applicable State in § 52.40(c)(2):

* * * * *

(e) *Recordkeeping requirements.* If you are the owner or operator of an affected unit, you shall maintain records of the following information for each day the affected unit operates during the ozone season consistent with the requirements of § 52.40(c)(3) and (f):

* * * * *

(f) * * *

(1) If you are the owner or operator of an affected unit, you shall submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after the date of completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(2) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that

occurred during the reporting period. Excess emissions are defined as any calculated 30-day rolling average NO_x emissions rate that exceeds the applicable emissions limit established under paragraph (c) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(3) If you are the owner or operator of an affected unit, you shall submit an annual report to the EPA by January 30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall include all records required by paragraph (e) of this section, including records of CEMS data or operating parameters required by paragraph (d) of this section to demonstrate continuous compliance with the applicable emissions limits under paragraph (c) of this section.

(g) * * *

(2) The owner or operator of an existing affected unit that emits or has a potential to emit 100 tons per year or more of NO_x as of August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii), shall notify the Administrator that the unit is subject to this section. The notification shall be submitted in PDF format via CEDRI or an analogous electronic submission system provided by the EPA not later than December 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [120 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). CEDRI can be accessed through the EPA's CDX (<https://cdx.epa.gov/>). The notification shall provide the following information:

* * * * *

■ 7. Amend § 52.43 by:

■ a. Revising paragraphs (b) and (d)(1), paragraph (d)(4) introductory text, and paragraphs (d)(4)(i) and (ii);

■ b. In paragraph (d)(4)(iii) introductory text, removing “via the CEDRI or analogous” and adding in its place “in writing or via an”;

■ c. In paragraph (d)(4)(iii)(B), removing “in writing, within” and adding in its

place “via CEDRI or an analogous electronic submission system provided by the EPA, within”;

■ d. Revising paragraph (d)(4)(iv);

■ e. In paragraph (d)(4)(v), removing “August 5, 2024, the” and adding in its place “the submission deadline specified for the unit in paragraph (d)(1) of this section, the”;

■ f. In paragraph (e)(3) introductory text, removing “2026 ozone season” and adding in its place “start date of the first ozone season identified for the applicable State in § 52.40(c)(2)”;

■ g. In paragraph (e)(3)(ii), removing “a site-specific indicator” and adding in its place “site-specific indicator ranges”;

■ h. In paragraph (e)(3)(iv), removing “paragraph (f)” and adding in its place “paragraph (g)”;

■ i. Revising paragraph (f) introductory text;

■ j. In paragraph (f)(8), removing “paragraph (d)” and adding in its place “paragraph (e)”;

■ k. Revising paragraphs (g)(1) through (4) and paragraph (h)(2) introductory text.

The revisions read as follows:

§ 52.43 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from the Iron and Steel Mills and Ferroalloy Manufacturing Industry?

* * * * *

(b) *Applicability.* The requirements of this section apply to each new or existing rehear furnace at an iron and steel mill or ferroalloy manufacturing facility that is located within any of the States listed in § 52.40(c)(2), including Indian country located within the borders of any such State(s), does not have low-NO_x burners installed, and directly emits or has the potential to emit 100 tons per year or more of NO_x on or after August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). Any existing rehear furnace without low-NO_x burners installed and with a potential to emit of 100 tons per year or more of NO_x on the date specified for the unit in the preceding sentence will continue to be subject to the requirements of this section even if that unit later installs low-NO_x burners or becomes subject to a physical or operational limitation that lowers its potential to emit below 100 tons per year of NO_x.

* * * * *

(d) * * *

(1) The owner or operator of each affected unit must submit a work plan for each affected unit by August 5, 2024,

for a unit in a State listed in § 52.40(c)(2)(i), or [ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). The work plan must be submitted via CEDRI or an analogous electronic submission system provided by the EPA. Each work plan must include a description of the affected unit and rated production and energy capacities, identification of the low-NO_x burner or alternative low NO_x technology selected, and the phased construction timeframe by which you will design, install, and consistently operate the device. Each work plan shall also include, where applicable, performance test results obtained no more than five years before August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii), to be used as baseline emissions testing data providing the basis for required emissions reductions. If no such data exist, then the owner or operator must perform pre-installation testing as described in paragraph (e)(3) of this section.

* * * * *

(4) The Administrator will act as follows with respect to each submitted work plan:

(i) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of an affected unit if the submitted work plan is complete, that is, whether the submission contains sufficient information to make a determination, within 60 calendar days after receipt of the original work plan and within 60 calendar days after receipt of any supplementary information.

(ii) The Administrator will provide notification in writing or via an electronic submission system provided by the EPA to the owner or operator of a decision to approve or intention to disapprove the work plan within 60 calendar days after providing written notification pursuant to paragraph (d)(4)(i) of this section that the submitted work plan is complete. Any decision to approve a work plan will be made publicly available.

* * * * *

(iv) The Administrator's final decision to disapprove a work plan will be provided in writing or via an electronic submission system provided by the EPA, will be made publicly available, and will set forth the specific grounds on which the disapproval is based. The final decision will be made within 60 calendar days after presentation of

additional information or argument (if the submitted work plan is complete), or within 60 calendar days after the deadline for the submission of additional information or argument under paragraph (d)(4)(iii)(B) of this section, if no such submission is made.

* * * * *

(f) *Recordkeeping requirements.* If you are the owner or operator of an affected unit, you shall maintain records of the following information for each day the affected unit operates during the ozone season consistent with the requirements of § 52.40(c)(3) and (f):

* * * * *

(g) * * *

(1) If you are the owner or operator of an affected unit, you shall submit a final report via CEDRI or an analogous electronic submission system provided by the EPA, by no later than one month before the start date of the first ozone season identified for the applicable State in § 52.40(c)(2), certifying that installation of each selected control device has been completed. You shall include in the report the dates of final construction and relevant performance testing, where applicable, demonstrating compliance with the selected emission limits pursuant to paragraphs (c) and (d) of this section.

(2) If you are the owner or operator of an affected unit, you must submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after the date of completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(3) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that occurred during the reporting period. Excess emissions are defined as any calculated 30-day rolling average NO_x emissions rate that exceeds the applicable emissions limit established under paragraphs (c) and (d) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(4) If you are the owner or operator of an affected unit, you shall submit an annual report to the EPA by January

30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall include all records required by paragraph (f) of this section, including records of CEMS data or operating parameters required by paragraph (e) of this section to demonstrate compliance with the applicable emissions limits established under paragraphs (c) and (d) of this section.

(h) * * *

(2) The owner or operator of an existing affected unit that does not have low-NO_x burners installed and that emits or has a potential to emit 100 tons per year or more of NO_x as of August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii), shall notify the Administrator that the unit is subject to this section. The notification shall be submitted in PDF format via CEDRI or an analogous electronic submission system provided by the EPA not later than December 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [120 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). CEDRI can be accessed through the EPA's CDX (<https://cdx.epa.gov/>). The notification shall provide the following information:

* * * * *

■ 8. Amend § 52.44 by:

■ a. In paragraph (a):

■ i. In the definition for "Affected units", removing "Affected units means" and adding "Affected unit means"; and

■ ii. Revising the definition "Wool fiberglass";

■ b. Revising paragraph (b) and paragraph (c) introductory text;

■ c. In paragraph (d)(1) introductory text and paragraph (e)(1) introductory text, removing "the CEDRI or" and adding in its place "CEDRI or an";

■ d. In paragraph (g)(3) introductory text, removing "2026 ozone season" and adding in its place "start date of the first ozone season identified for the applicable State in § 52.40(c)(2)";

■ e. In paragraph (g)(3)(ii), removing "a";

■ f. In paragraph (g)(3)(iv), removing "paragraph (h)" and adding in its place "paragraph (i)";

■ g. Revising paragraph (h)(1) introductory text;

- h. Redesignating paragraphs (h)(1)(vii)(D), (h)(1)(viii), and (h)(1)(ix) as paragraphs (h)(1)(viii), (h)(1)(ix), and (h)(1)(x), respectively;
- i. In paragraph (h)(2), adding a second sentence;
- j. In paragraph (h)(3), adding a third sentence; and
- k. Revising paragraphs (i)(1) through (3) and paragraph (j)(2) introductory text.

The revisions and additions read as follows:

§ 52.44 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from the Glass and Glass Product Manufacturing Industry?

(a) * * *

Wool fiberglass means fibrous glass of random texture, including acoustical board and tile (mineral wool), fiberglass insulation, glass wool, insulation (rock wool, fiberglass, slag, and silica minerals), and mineral wool roofing mats.

(b) *Applicability.* You are subject to the requirements under this section if you own or operate a new or existing glass manufacturing furnace that is located within any of the States listed in § 52.40(c)(2), including Indian country located within the borders of any such State(s), and directly emits or has the potential to emit 100 tons per year or more of NO_x on or after August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). Any existing glass manufacturing furnace with a potential to emit of 100 tons per year or more of NO_x on the date specified for the unit in the preceding sentence will continue to be subject to the requirements of this section even if that unit later becomes subject to a physical or operational limitation that lowers its potential to emit below 100 tons per year of NO_x.

(c) *Emissions limitations.* If you are the owner or operator of an affected unit, you must meet the emissions limitations in paragraphs (c)(1) and (2) of this section on a 30-day rolling average basis during each ozone season identified for the applicable State in § 52.40(c)(2), provided that such emissions limitations shall not apply to the unit during startup, shutdown, and/or idling in any ozone season for which the unit complies with the startup requirements in paragraph (d) of this section, the shutdown requirements in paragraph (e) of this section, and/or the idling requirements in paragraph (f) of this section, respectively.

* * * * *

(h) * * *

(1) If you are the owner or operator of an affected unit, you shall maintain records of the following information for each day the affected unit operates during the ozone season consistent with the requirements of § 52.40(c)(3) and (f):

* * * * *

(2) * * * The records shall be maintained consistent with the requirements of § 52.40(c)(3) and (f).

(3) * * * The records shall be maintained consistent with the requirements of § 52.40(c)(3) and (f).

(i) * * *

(1) If you are the owner or operator of an affected unit, you must submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after the date of completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(2) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that occurred during the reporting period. Excess emissions are defined as any calculated 30-day rolling average NO_x emissions rate that exceeds the applicable emissions limit in paragraph (c) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(3) If you own or operate an affected unit, you shall submit an annual report to the EPA by January 30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall include all records required by paragraph (h) of this section, including records of CEMS data or operating parameters required by paragraph (g) of this section to demonstrate continuous compliance with the applicable emissions limits under paragraph (c) of this section.

(j) * * *

(2) The owner or operator of an existing affected unit that emits or has

a potential to emit 100 tons per year or more of NO_x as of August 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii), shall notify the Administrator that the unit is subject to this section. The notification shall be submitted in PDF format via CEDRI or an analogous electronic submission system provided by the EPA not later than December 4, 2023, for a unit in a State listed in § 52.40(c)(2)(i), or [120 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], for a unit in a State listed in § 52.40(c)(2)(ii). CEDRI can be accessed through the EPA's CDX (<https://cdx.epa.gov/>). The notification shall provide the following information:

* * * * *

■ 9. Amend § 52.45 by:

- a. Revising the section heading;
- b. In paragraph (a), in the definition for “Maximum heat input capacity”, removing the second “means” before “the ability”;
- c. Revising paragraph (b)(1);
- d. In paragraph (b)(2) introductory text, removing “paragraph (f)(2)” and adding in its place “paragraphs (e)(2) and (f)(3)”;
- e. Revising paragraph (b)(2)(i) and paragraph (c) introductory text;
- f. In paragraph (d)(1) introductory text, removing “May 1, 2026” and adding in its place “the start date of the first ozone season identified for the applicable State in § 52.40(c)(2)”;
- g. In paragraph (d)(1)(i), removing “emission rate” and adding in its place “emissions rate”;
- h. In paragraph (d)(2) introductory text, removing “mmBTU/hr” and adding in its place “mmBtu/hr”;
- i. Revising paragraph (d)(2)(iii);
- j. In paragraph (d)(2)(v), removing “coal and span value” and adding in its place “coal and a span value”;
- k. Revising paragraph (d)(2)(vii) and paragraph (d)(3) introductory text;
- l. In paragraph (d)(3)(ii), removing “affected units operates” and adding in its place “affected unit operates”;
- m. In paragraphs (d)(3)(iii)(A) and (B), removing “emission rates” and adding in its place “emissions rates”;
- n. Adding paragraph (d)(3)(iv);
- o. Removing paragraph (d)(4);
- p. Revising paragraph (e)(1) introductory text, paragraph (e)(2) introductory text, and paragraphs (e)(2)(v) and (f)(1) through (3); and
- q. Removing paragraph (f)(4).

The revisions and addition read as follows:

§ 52.45 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from the Basic Chemical Manufacturing, Petroleum and Coal Products Manufacturing, Pulp, Paper, and Paperboard Mills, Metal Ore Mining, and Iron and Steel Mills and Ferroalloy Manufacturing Industries?

* * * * *

(b) * * *

(1) The requirements of this section apply to each new or existing boiler with a design capacity of 100 mmBtu/hr or greater that received 90% or more of its heat input from coal, residual oil, distillate oil, natural gas, or combinations of these fuels in the previous ozone season; is located at sources that are within the Basic Chemical Manufacturing industry, the Petroleum and Coal Products Manufacturing industry, the Pulp, Paper, and Paperboard Mills industry, the Metal Ore Mining industry, and the Iron and Steel Mills and Ferroalloy Manufacturing industry; and is located within any of the States listed in § 52.40(c)(2), including Indian country located within the borders of any such State(s). The requirements of this section do not apply to an emissions unit that meets the requirements for a low-use exemption as provided in paragraph (b)(2) of this section.

* * * * *

(2) * * *

(i) If you are the owner or operator of an affected unit that exceeds the 10% per year hour of operation over three years criterion or the 20% hours of operation per year criterion, you can no longer comply via the low-use exemption provisions and must meet the applicable emissions limits and other applicable provisions as soon as possible but not later than one year from the date eligibility as a low-use boiler was negated by exceedance of the low-use boiler criteria.

* * * * *

(c) *Emissions limitations.* If you are the owner or operator of an affected unit, you must meet the following emissions limitations on a 30-day rolling average basis during each ozone season identified for the applicable State in § 52.40(c)(2):

* * * * *

(d) * * *

(2) * * *

(iii) The 1-hour average NO_x emissions rates measured by the CEMS shall be expressed in terms of lbs/mmBtu heat input and shall be used to calculate the average emissions rates under paragraph (c) of this section.

* * * * *

(vii) You may delay installing a CEMS for NO_x until after the initial performance test has been conducted. If you demonstrate during the performance test that emissions of NO_x are less than 70 percent of the applicable emissions limit in paragraph (c) of this section, you are not required to install a CEMS for measuring NO_x. If you demonstrate your affected unit emits less than 70 percent of the applicable emissions limit and choose to not install a CEMS, you must submit a request via CEDRI or an analogous electronic submission system provided by the EPA to the Administrator that documents the results of the initial performance test and includes an alternative monitoring procedure that will be used to track compliance with the applicable NO_x emissions limit(s) in paragraph (c) of this section. The Administrator may consider the request and, following public notice and comment, may approve the alternative monitoring procedure with or without revision, or disapprove the request. If the Administrator approves the request for the alternative monitoring procedure, you must request that the relevant permitting agency incorporate the monitoring procedure into the facility's title V permit. Upon receipt of a disapproved request, you will have one year to install a CEMS.

(3) If you are the owner or operator of an affected unit with a heat input capacity less than 250 mmBtu/hr, you must monitor NO_x emissions via the requirements of paragraph (d)(2) of this section or you must monitor NO_x emissions by conducting an annual test in conjunction with the implementation of a monitoring plan meeting the following requirements:

* * * * *

(iv) You shall submit the monitoring plan to the EPA via CEDRI or an analogous electronic submission system provided by the EPA, and request that the relevant permitting agency incorporate the monitoring plan into the facility's title V permit.

(e) * * *

(1) If you are the owner or operator of an affected unit which is not a low-use boiler, you shall maintain records of the following information for each day the affected unit operates during the ozone season consistent with the requirements of § 52.40(c)(3) and (f):

* * * * *

(2) If you are the owner or operator of an affected unit complying as a low-use boiler, you must maintain the following records for each operating day of the

calendar year consistent with the requirements of § 52.40(f):

* * * * *

(v) The annual hours of operation for each of the prior 3 years, and the 3-year average hours of operation.

(f) * * *

(1) If you are the owner or operator of an affected unit, you must submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after the date of completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(2) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that occurred during the reporting period. Excess emissions are defined as any calculated 30-day rolling average NO_x emissions rate, as determined under paragraph (e)(1)(iii) of this section, that exceeds the applicable emissions limit in paragraph (c) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(3) If you are the owner or operator of an affected unit, you shall submit an annual report to the EPA by January 30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall include all records required by paragraph (e) of this section, including records of CEMS data or operating parameters required by paragraph (d) of this section to demonstrate continuous compliance with the applicable emissions limits under paragraph (c) of this section.

■ 10. Amend § 52.46 by:

■ a. In paragraph (a):

■ i. Removing the definitions “mass burn refractory waste combustor”, “mass burn rotary waterwall municipal waste combustor”, and “mass burn waterwall municipal waste combustor”;
 ■ ii. Adding the definition “Municipal solid waste or MSW” in alphabetical order; and

- iii. In the definition for “Municipal waste combustor, MWC, or municipal waste combustor unit”, paragraph (i), removing “Means any” and adding in its place “Any”;
 - b. In paragraph (b), removing “and”;
 - c. Revising paragraph (c) introductory text;
 - d. In paragraphs (c)(1) and (2), removing “at 7 percent oxygen”;
 - e. Removing and reserving paragraph (d)(1);
 - f. Revising paragraph (d)(2);
 - g. In paragraph (d)(5), removing “owner and operator” and adding in its place “owner or operator”;
 - h. In paragraph (e)(1) introductory text, removing “NO_x are” and adding in its place “NO_x emissions are”;
 - i. Revising paragraph (e)(1)(vi) introductory text and paragraphs (e)(1)(vi)(A), (e)(2)(vi)(B), and (e)(2)(vii);
 - j. In paragraph (e)(2)(viii), removing “paragraph (e)(2)(iv)” and adding in its place “paragraph (e)(2)(vi)”;
 - k. Removing and reserving paragraph (e)(3);
 - l. Revising paragraph (f) introductory text and paragraph (f)(3);
 - m. In paragraph (f)(4), removing “occurrence that” and adding in its place “occurrence where”;
 - n. Revising paragraphs (g)(1) and (2); and
 - o. Adding paragraph (g)(3).
- The additions and revisions read as follows:

§ 52.46 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from Municipal Waste Combustors?

(a) * * *

Municipal solid waste or MSW means “municipal solid waste or municipal-type solid waste or MSW” as defined in 40 CFR 60.51b.

(c) *Emissions limitations.* If you are the owner or operator of an affected unit, you must meet the following emissions limitations at all times on a 24-hour block average basis and a 30-day rolling average basis during each ozone season identified for the applicable State in § 52.40(c)(2), using NO_x measurements corrected to 7 percent oxygen except as otherwise provided in paragraph (e)(2)(vi)(B) of this section:

- (d) * * *
- (2) Duration of startup and shutdown periods is limited to 3 hours per occurrence.
- (e) * * *
- (1) * * *

(vi) If you select carbon dioxide for use in diluent corrections, you shall follow the requirements of 40 CFR 60.58b(b)(6) to establish the relationship between oxygen and carbon dioxide levels:

(A) This relationship shall be established during the initial performance test and may be reestablished during performance compliance tests; and

* * *

(2) * * *

(vi) * * *

(B) Each NO_x 1-hour arithmetic average shall be corrected to 7 percent oxygen on an hourly basis using the 1-hour arithmetic average of the oxygen (or carbon dioxide) CEMS data, except that NO_x data for an hour identified as falling within a period of startup or shutdown in accordance with paragraphs (d)(2) through (4) of this section can reflect NO_x as measured at stack oxygen content without such correction.

(vii) The 1-hour arithmetic averages shall be expressed in parts per million by volume (dry basis) and shall be used to calculate the 24-hour daily arithmetic average concentrations. The 1-hour arithmetic averages shall be calculated using the data points required under 40 CFR 60.13(e)(2).

* * *

(f) *Recordkeeping requirements.* If you are the owner or operator of an affected unit, you shall maintain records of the following information, as applicable, for each day the affected unit operates during the ozone season consistent with the requirements of § 52.40(c)(3) and (f):

* * *

(3) Identification of the calendar dates and times (hours) for which valid hourly NO_x emissions data have not been obtained, including reasons for not obtaining the data and a description of corrective actions taken.

* * *

(g) * * *

(1) If you are the owner or operator of an affected unit, you must submit the results of the performance test or performance evaluation of the CEMS to the EPA within 60 days after the date of completing each performance test required by this section. The results must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section.

(2) If you are the owner or operator of an affected unit, you are required to submit excess emissions reports to the EPA for any excess emissions that occurred during the reporting period.

Excess emissions are defined as any calculated 24-hour block average NO_x emissions rate or calculated 30-day rolling average NO_x emissions rate, as determined under paragraph (e)(2) of this section, that exceeds the respective emissions limit in paragraph (c) of this section. Excess emissions reports must be submitted following the procedures specified in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI.

(3) If you are the owner or operator of an affected unit, you shall submit an annual report to the EPA by January 30th of each year. Annual reports must be submitted following the procedures in § 52.40(g) via CEDRI or an analogous electronic reporting approach provided by the EPA to report data required by this section. Submissions made via CEDRI must be made in accordance with the appropriate submission instructions provided in CEDRI. The report shall include all information required by paragraph (f) of this section, including records of CEMS data required by paragraph (e) of this section to demonstrate compliance with the applicable emissions limits under paragraph (c) of this section.

Subpart D—Arizona

- 11. Add § 52.154 to subpart D to read as follows:

§ 52.154 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

(a)(1) The owner and operator of each source and each unit located in the State of Arizona and Indian country within the borders of the State and for which requirements are set forth under the CSAPR NO_x Ozone Season Group 3 Trading Program in subpart GGGGG of part 97 of this chapter must comply with such requirements with regard to emissions occurring in 2025 and each subsequent year. The obligation to comply with such requirements with regard to sources and units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority will be eliminated by the promulgation of an approval by the Administrator of a revision to Arizona's State Implementation Plan (SIP) as correcting the SIP's deficiency that is the basis for the CSAPR Federal Implementation Plan (FIP) under § 52.38(b)(1) and (b)(2)(iii) for those sources and units, except to the extent

the Administrator's approval is partial or conditional. The obligation to comply with such requirements with regard to sources and units located in areas of Indian country within the borders of the State not subject to the State's SIP authority will not be eliminated by the promulgation of an approval by the Administrator of a revision to Arizona's SIP.

(2) Notwithstanding the provisions of paragraph (a)(1) of this section, if, at the time of the approval of Arizona's SIP revision described in paragraph (a)(1) of this section, the Administrator has already started recording any allocations of CSAPR NO_x Ozone Season Group 3 allowances under subpart GGGGG of part 97 of this chapter to units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority for a control period in any year, the provisions of subpart GGGGG of part 97 of this chapter authorizing the Administrator to complete the allocation and recordation of CSAPR NO_x Ozone Season Group 3 allowances to such units for each such control period shall continue to apply, unless provided otherwise by such approval of the State's SIP revision.

(b) The owner and operator of each source located in the State of Arizona and Indian country within the borders of the State and for which requirements are set forth in § 52.40 and § 52.41, § 52.42, § 52.43, § 52.44, § 52.45, or § 52.46 must comply with such requirements with regard to emissions occurring in 2027 and each subsequent year.

Subpart Q—Iowa

■ 12. Amend § 52.840 by:

■ a. In paragraph (b)(2):

■ i. Removing “2017 and each subsequent year.” and adding in its place “2017 through 2024.”; and

■ ii. Removing the second and third sentences;

■ b. Revising paragraph (b)(3); and

■ c. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 52.840 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(b) * * *

(3) The owner and operator of each source and each unit located in the State of Iowa and Indian country within the borders of the State and for which requirements are set forth under the CSAPR NO_x Ozone Season Group 3 Trading Program in subpart GGGGG of part 97 of this chapter must comply

with such requirements with regard to emissions occurring in 2025 and each subsequent year. The obligation to comply with such requirements with regard to sources and units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority will be eliminated by the promulgation of an approval by the Administrator of a revision to Iowa's State Implementation Plan (SIP) as correcting the SIP's deficiency that is the basis for the CSAPR Federal Implementation Plan (FIP) under § 52.38(b)(1) and (b)(2)(iii), except to the extent the Administrator's approval is partial or conditional. The obligation to comply with such requirements with regard to sources and units located in areas of Indian country within the borders of the State not subject to the State's SIP authority will not be eliminated by the promulgation of an approval by the Administrator of a revision to Iowa's SIP.

(4) Notwithstanding the provisions of paragraph (b)(3) of this section, if, at the time of the approval of Iowa's SIP revision described in paragraph (b)(3) of this section, the Administrator has already started recording any allocations of CSAPR NO_x Ozone Season Group 3 allowances under subpart GGGGG of part 97 of this chapter to units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority for a control period in any year, the provisions of subpart GGGGG of part 97 of this chapter authorizing the Administrator to complete the allocation and recordation of CSAPR NO_x Ozone Season Group 3 allowances to such units for each such control period shall continue to apply, unless provided otherwise by such approval of the State's SIP revision.

(5) Notwithstanding the provisions of paragraph (b)(2) of this section, after 2024 the provisions of § 97.826(c) of this chapter (concerning the transfer of CSAPR NO_x Ozone Season Group 2 allowances between certain accounts under common control) and the provisions of § 97.826(f) of this chapter (concerning the conversion of amounts of unused CSAPR NO_x Ozone Season Group 2 allowances allocated for control periods before 2025 to different amounts of CSAPR NO_x Ozone Season Group 3 allowances) shall continue to apply.

Subpart R—Kansas

■ 13. Amend § 52.882 by:

■ a. In paragraph (b)(1):

■ i. Removing “2017 and each subsequent year.” and adding in its place “2017 through 2024.”; and

■ ii. Removing the second and third sentences;

■ b. Revising paragraph (b)(2); and

■ c. Adding paragraphs (b)(3) and (4).

The revision and additions read as follows:

§ 52.882 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(b) * * *

(2) The owner and operator of each source and each unit located in the State of Kansas and Indian country within the borders of the State and for which requirements are set forth under the CSAPR NO_x Ozone Season Group 3 Trading Program in subpart GGGGG of part 97 of this chapter must comply with such requirements with regard to emissions occurring in 2025 and each subsequent year. The obligation to comply with such requirements with regard to sources and units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority will be eliminated by the promulgation of an approval by the Administrator of a revision to Kansas' State Implementation Plan (SIP) as correcting the SIP's deficiency that is the basis for the CSAPR Federal Implementation Plan (FIP) under § 52.38(b)(1) and (b)(2)(iii), except to the extent the Administrator's approval is partial or conditional. The obligation to comply with such requirements with regard to sources and units located in areas of Indian country within the borders of the State not subject to the State's SIP authority will not be eliminated by the promulgation of an approval by the Administrator of a revision to Kansas' SIP.

(3) Notwithstanding the provisions of paragraph (b)(2) of this section, if, at the time of the approval of Kansas' SIP revision described in paragraph (b)(2) of this section, the Administrator has already started recording any allocations of CSAPR NO_x Ozone Season Group 3 allowances under subpart GGGGG of part 97 of this chapter to units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority for a control period in any year, the provisions of subpart GGGGG of part 97 of this chapter authorizing the Administrator to complete the allocation and recordation of CSAPR NO_x Ozone Season Group 3 allowances to such units for each such control period shall continue to apply, unless provided otherwise by such approval of the State's SIP revision.

(4) Notwithstanding the provisions of paragraph (b)(1) of this section, after 2024 the provisions of § 97.826(c) of this chapter (concerning the transfer of CSAPR NO_x Ozone Season Group 2 allowances between certain accounts under common control) and the provisions of § 97.826(f) of this chapter (concerning the conversion of amounts of unused CSAPR NO_x Ozone Season Group 2 allowances allocated for control periods before 2025 to different amounts of CSAPR NO_x Ozone Season Group 3 allowances) shall continue to apply.

Subpart GG—New Mexico

- 14. Add § 52.1641 to subpart GG to read as follows:

§ 52.1641 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

(a) The owner and operator of each source and each unit located in the State of New Mexico and Indian country within the borders of the State and for which requirements are set forth under the CSAPR NO_x Ozone Season Group 3 Trading Program in subpart GGGGG of part 97 of this chapter must comply with such requirements with regard to emissions occurring in 2025 and each subsequent year. The obligation to comply with such requirements with regard to sources and units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority will be eliminated by the promulgation of an approval by the Administrator of a revision to New Mexico's State Implementation Plan (SIP) as correcting the SIP's deficiency that is the basis for the CSAPR Federal Implementation Plan (FIP) under § 52.38(b)(1) and (b)(2)(iii) for those sources and units, except to the extent the Administrator's approval is partial or conditional. The obligation to comply with such requirements with regard to sources and units located in areas of Indian country within the borders of the State not subject to the State's SIP authority will not be eliminated by the promulgation of an approval by the Administrator of a revision to New Mexico SIP.

(b) Notwithstanding the provisions of paragraph (a) of this section, if, at the time of the approval of New Mexico's SIP revision described in paragraph (a) of this section, the Administrator has already started recording any allocations of CSAPR NO_x Ozone Season Group 3 allowances under subpart GGGGG of part 97 of this chapter to units in the State and areas of Indian country within the borders of the State subject to the State's SIP authority for a control period

in any year, the provisions of subpart GGGGG of part 97 of this chapter authorizing the Administrator to complete the allocation and recordation of CSAPR NO_x Ozone Season Group 3 allowances to such units for each such control period shall continue to apply, unless provided otherwise by such approval of the State's SIP revision.

Subpart RR—Tennessee

- 15. Amend § 52.2240 by:
 - a. In paragraph (e)(2):
 - i. Removing “2017 and each subsequent year.” and adding in its place “2017 through 2024.”; and
 - ii. Removing the second sentence;
 - b. Revising paragraph (e)(3); and
 - c. Adding paragraphs (e)(4) and (5).
 The revision and additions read as follows:

§ 52.2240 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(e) * * *

(3) The owner and operator of each source and each unit located in the State of Tennessee and for which requirements are set forth under the CSAPR NO_x Ozone Season Group 3 Trading Program in subpart GGGGG of part 97 of this chapter must comply with such requirements with regard to emissions occurring in 2025 and each subsequent year. The obligation to comply with such requirements will be eliminated by the promulgation of an approval by the Administrator of a revision to Tennessee's State Implementation Plan (SIP) as correcting the SIP's deficiency that is the basis for the CSAPR Federal Implementation Plan (FIP) under § 52.38(b)(1) and (b)(2)(iii), except to the extent the Administrator's approval is partial or conditional.

(4) Notwithstanding the provisions of paragraph (e)(3) of this section, if, at the time of the approval of Tennessee's SIP revision described in paragraph (e)(3) of this section, the Administrator has already started recording any allocations of CSAPR NO_x Ozone Season Group 3 allowances under subpart GGGGG of part 97 of this chapter to units in the State for a control period in any year, the provisions of subpart GGGGG of part 97 of this chapter authorizing the Administrator to complete the allocation and recordation of CSAPR NO_x Ozone Season Group 3 allowances to such units for each such control period shall continue to apply, unless provided otherwise by such approval of the State's SIP revision.

(5) Notwithstanding the provisions of paragraph (e)(2) of this section, after 2024 the provisions of § 97.826(c) of this chapter (concerning the transfer of CSAPR NO_x Ozone Season Group 2 allowances between certain accounts under common control) and the provisions of § 97.826(f) of this chapter (concerning the conversion of amounts of unused CSAPR NO_x Ozone Season Group 2 allowances allocated for control periods before 2025 to different amounts of CSAPR NO_x Ozone Season Group 3 allowances) shall continue to apply.

PART 97—FEDERAL NO_x BUDGET TRADING PROGRAM, CAIR NO_x AND SO₂ TRADING PROGRAMS, CSAPR NO_x AND SO₂ TRADING PROGRAMS, AND TEXAS SO₂ TRADING PROGRAM

- 16. The authority citation for part 97 continues to read as follows:

Authority: 42 U.S.C. 7401, 7403, 7410, 7426, 7491, 7601, and 7651, *et seq.*

Subpart BBBB—CSAPR NO_x Ozone Season Group 1 Trading Program

§ 97.502 [Amended]

- 17. Amend § 97.502 in the definition for “CSAPR NO_x Ozone Season Group 3 allowance” by removing “§ 97.826(d) or (e), or” and adding in its place “§ 97.826(d), (e), or (f), or”.
- 18. Amend § 97.526 by adding paragraphs (d)(2)(iv) and (e)(4) to read as follows:

§ 97.526 Banking and conversion.

* * * * *

(d) * * *

(2) * * *

(iv) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and § 97.826(f)(1), upon any determination that would otherwise result in the initial recordation of a given number of CSAPR NO_x Ozone Season Group 1 allowances in the compliance account for a source in a State listed in § 52.38(b)(2)(iii)(E) of this chapter (and Indian country within the borders of such a State), the Administrator will not record such CSAPR NO_x Ozone Season Group 1 allowances but instead will allocate and record in such account an amount of CSAPR NO_x Ozone Season Group 3 allowances for the control period in 2023 computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_x Ozone Season Group 1 allowances divided by the conversion factor determined under paragraph (d)(1)(ii) of this section and further divided by the conversion factor determined under § 97.826(f)(1)(ii).

(e) * * *

(4) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and § 97.826(f)(1), the owner or operator of a CSAPR NO_x Ozone Season Group 1 source in a State listed in § 52.38(b)(2)(ii)(A) of this chapter (and Indian country within the borders of such a State) may satisfy a requirement to hold a given number of CSAPR NO_x Ozone Season Group 1 allowances for the control period in 2015 or 2016 by holding instead, in a general account established for this sole purpose, an amount of CSAPR NO_x Ozone Season Group 3 allowances for the control period in 2025 (or any later control period for which the allowance transfer deadline defined in § 97.1002 has passed) computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_x Ozone Season Group 1 allowances divided by the conversion factor determined under paragraph (d)(1)(ii) of this section and further divided by the conversion factor determined under § 97.826(f)(1)(ii).

Subpart EEEEE—CSAPR NO_x Ozone Season Group 2 Trading Program

§ 97.802 [Amended]

- 19. Amend § 97.802 by:
 - a. In the definition for “Allocate or allocation”, removing “§§ 97.526(d), 97.826(d), and 97.1026(e), and” and adding in its place “§§ 97.526 and 97.1026, and”;
 - b. In the definition for “Common designated representative’s assurance level”, paragraph (2), removing “§ 97.526(d), § 97.826(d), or § 97.1026(e).” and adding in its place “§ 97.526, § 97.826, or § 97.1026.”; and
 - c. In the definition for “CSAPR NO_x Ozone Season Group 3 allowance”, removing “§ 97.826(d) or (e), or” and adding in its place “§ 97.826(d), (e), or (f), or”.

§ 97.810 [Amended]

- 20. Amend § 97.810 in paragraphs (a)(6)(i) through (iii), (a)(7)(i) through (iii), (a)(19)(i) and (ii), and (b)(6), (7), and (19) by removing “and thereafter” and adding in its place “through 2024”.

§ 97.811 [Amended]

- 21. Amend § 97.811(d) heading by adding “Original” before “Group 2 allowances”.

§ 97.824 [Amended]

- 22. Amend § 97.824(c)(2)(ii) by removing “§ 97.526(d), § 97.826(d), or § 97.1026(e), in” and adding in its place “§ 97.526, § 97.826, or § 97.1026, in”.
- 23. Amend § 97.826 by:
 - a. Revising paragraph (e)(1)(ii)(B);

- b. Redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f);
- c. In newly redesignated paragraph (g) introductory text, removing “this paragraph (f)” and adding in its place “this paragraph (g)”;
- d. In newly redesignated paragraph (g)(1)(i), removing “paragraph (f)(1)(ii)” and adding in its place “paragraph (g)(1)(ii)”;
- e. Adding paragraph (g)(3).

The revision and additions read as follows:

§ 97.826 Banking and conversion.

* * * * *

(e) * * *

(1) * * *

(ii) * * *

(B) The product of the sum of the trading budgets for the control period in 2024 under § 97.1010(a)(1)(i) for all States listed in § 52.38(b)(2)(iii)(B) and (C) of this chapter multiplied by 0.21 and further multiplied by a fraction whose numerator is the number of days from August 4, 2023, through September 30, 2023, inclusive, and whose denominator is 153.

* * * * *

(f) Notwithstanding any other provision of this subpart, part 52 of this chapter, or any SIP revision approved under § 52.38(b)(8) or (9) of this chapter:

(1) As soon as practicable on or after [45 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], the Administrator will temporarily suspend acceptance of CSAPR NO_x Ozone Season Group 2 allowance transfers submitted under § 97.822 and, before resuming acceptance of such transfers, will take the following actions with regard to every compliance account for a CSAPR NO_x Ozone Season Group 2 source in a State listed in § 52.38(b)(2)(iii)(E) of this chapter (and Indian country within the borders of such a State):

(i) The Administrator will deduct all CSAPR NO_x Ozone Season Original Group 2 allowances allocated for the control periods in 2017 through 2024 from each such account.

(ii) The Administrator will determine a conversion factor equal to the greater of 1.0000 or the quotient, expressed to four decimal places, of—

(A) The sum of all CSAPR NO_x Ozone Season Original Group 2 allowances deducted from all such accounts under paragraph (e)(1)(i) of this section; divided by

(B) The product of the sum of the preset trading budgets for the control period in 2025 under § 97.1010(a)(2)(i) for all States listed in § 52.38(b)(2)(iii)(E) of this chapter multiplied by 0.21.

(iii) The Administrator will allocate and record in each such account an amount of CSAPR NO_x Ozone Season Group 3 allowances for the control period in 2025 computed as the quotient, rounded up to the nearest allowance, of the number of CSAPR NO_x Ozone Season Original Group 2 allowances deducted from such account under paragraph (f)(1)(i) of this section divided by the conversion factor determined under paragraph (f)(1)(ii) of this section.

(2) After the Administrator has carried out the procedures set forth in paragraph (f)(1) of this section, upon any determination that would otherwise result in the initial recordation of a given number of CSAPR NO_x Ozone Season Original Group 2 allowances in the compliance account for a source in a State listed in § 52.38(b)(2)(iii)(E) of this chapter (and Indian country within the borders of such a State), the Administrator will not record such CSAPR NO_x Ozone Season Original Group 2 allowances but instead will allocate and record in such account an amount of CSAPR NO_x Ozone Season Group 3 allowances for the control period in 2025 computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_x Ozone Season Original Group 2 allowances divided by the conversion factor determined under paragraph (f)(1)(ii) of this section.

(g) * * *

(3) After the Administrator has carried out the procedures set forth in paragraph (f)(1) of this section, the owner or operator of a CSAPR NO_x Ozone Season Group 2 source in a State listed in § 52.38(b)(2)(ii)(A) of this chapter (and Indian country within the borders of such a State) may satisfy a requirement to hold a given number of CSAPR NO_x Ozone Season Original Group 2 allowances for a control period in 2017 through 2024 by holding instead, in a general account established for this sole purpose, an amount of CSAPR NO_x Ozone Season Group 3 allowances for the control period in 2025 (or any later control period for which the allowance transfer deadline defined in § 97.1002 has passed) computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_x Ozone Season Original Group 2 allowances divided by the conversion factor determined under paragraph (f)(1)(ii) of this section.

Subpart GGGGG—CSAPR NO_x Ozone Season Group 3 Trading Program

§ 97.1002 [Amended]

- 24. Amend § 97.1002 by:

■ a. In the definition for “Allocate or allocation”, removing “§§ 97.526(d) and 97.826(d) and (e), and” and adding in its place “§§ 97.526 and 97.826, and”;

■ b. In the definition for “Common designated representative’s assurance level”, paragraph (2), removing “§ 97.526(d) or § 97.826(d) or (e).” and adding in its place “§ 97.526 or § 97.826.”; and

■ c. In the definition for “CSAPR NO_x Ozone Season Group 3 allowance”, removing “§ 97.826(d) or (e), or” and adding in its place “§ 97.826(d), (e), or (f), or”.

■ 25. Amend § 97.1006 by:

■ a. Revising paragraph (c)(1)(i)(B);

■ b. In paragraph (c)(3)(i) introductory text, removing “paragraph (c)(3)(i)(A), (B), or (C)” and adding in its place “paragraphs (c)(3)(i)(A) through (D)”;

■ c. In paragraph (c)(3)(i)(A), removing the semicolon and adding in its place a period.

■ d. In paragraph (c)(3)(i)(B), removing “; or” and adding in its place a period.

■ e. Adding paragraph (c)(3)(i)(D); and

■ f. Revising paragraph (c)(3)(ii).

The revisions and addition read as follows:

§ 97.1006 Standard requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(B) Two times the sum, for all CSAPR NO_x Ozone Season Group 3 units at the source, of any excess over 50 tons of the sum for such a unit, for all calendar days of the control period, of any NO_x emissions on any calendar day of the control period exceeding the NO_x emissions that would have occurred on that calendar day if the unit had combusted the same daily heat input and emitted at any backstop daily NO_x emissions rate applicable to the unit for that control period.

* * * * *

(3) * * *

(i) * * *

(D) May 1, 2025, for a unit in a State (and Indian country within the borders of such State) listed in § 52.38(b)(2)(iii)(E) of this chapter.

(ii) A CSAPR NO_x Ozone Season Group 3 unit shall be subject to the requirements under paragraphs (c)(1)(iii) and (iv) of this section for the control period starting on the later of May 1, 2024, or the deadline applicable

to the unit under paragraph (c)(3)(i) of this section and for each control period thereafter.

* * * * *

■ 26. Amend § 97.1010 by:

■ a. In table 1 to paragraph (a)(1)(i) and table 2 to paragraph (a)(2)(i), adding the entries “Arizona”, “Iowa”, “Kansas”, “New Mexico”, and “Tennessee” in alphabetical order;

■ b. Revising paragraphs (a)(4)(ii)(B)(1) and (a)(4)(iii)(A);

■ c. In paragraph (a)(4)(iii)(B), adding “applicable” before “document referenced”;

■ d. Revising paragraphs (c)(2)(iii) and (iv); and

■ e. In table 6 to paragraph (e)(3)(i), adding the entries “Arizona”, “Iowa”, “Kansas”, “New Mexico”, and “Tennessee” in alphabetical order.

The additions and revisions read as follows:

§ 97.1010 State NO_x Ozone Season Group 3 trading budgets, set-asides, and variability limits.

(a) * * *

(1) * * *

(i) * * *

TABLE 1 TO PARAGRAPH (a)(1)(i)—STATE NO_x OZONE SEASON GROUP 3 TRADING BUDGETS BY CONTROL PERIOD, 2021–2025

[Tons]

State	2021	2022	Portion of 2023 control period before August 4, 2023, before prorating	Portion of 2023 control period on and after August 4, 2023, before prorating	2024	2025
Arizona	*	*	*	*	*	8,195
Iowa	*	*	*	*	*	9,752
Kansas	*	*	*	*	*	4,763
New Mexico	*	*	*	*	*	2,211
Tennessee	*	*	*	*	*	3,983
	*	*	*	*	*	

* * * * *

(2) * * *

(i) * * *

TABLE 2 TO PARAGRAPH (a)(2)(i)—PRESET TRADING BUDGETS BY CONTROL PERIOD, 2026–2029

[Tons]

State	2026	2027	2028	2029
Arizona	5,814	4,913	3,949	3,949

TABLE 2 TO PARAGRAPH (a)(2)(i)—PRESET TRADING BUDGETS BY CONTROL PERIOD, 2026–2029—Continued
[Tons]

State	2026	2027	2028	2029
Iowa	9,713	9,713	9,713	9,077
Kansas	4,763	4,763	4,763	4,763
New Mexico	2,008	2,008	2,008	2,008
Tennessee	3,983	2,666	2,130	1,198

* * * * *

(4) * * *

(ii) * * *

(B) * * *

(1) The sum for all units in the State meeting the criterion under paragraph (a)(4)(i)(A) of this section, without regard to whether such units also meet the criteria under paragraphs (a)(4)(i)(B) and (C) of this section, of the total heat input amounts reported in accordance with part 75 of this chapter for the historical control periods in the years two, three, and four years before the year of the control period for which the dynamic trading budget is being calculated, provided that for the historical control periods in 2022 and 2023, the total reported heat input amounts for Nevada and Utah as otherwise determined under this paragraph (a)(4)(ii)(B)(1) shall be increased by 13,489,332 mmBtu for Nevada and by 1,888,174 mmBtu for

Utah, and provided that for the historical control periods in 2022, 2023, and 2024, the total reported heat input amounts for Arizona and New Mexico as otherwise determined under this paragraph (a)(4)(ii)(B)(1) shall be increased by 13,304,261 mmBtu for Arizona and by 62,445 mmBtu for New Mexico;

* * * * *

(iii) * * *

(A) For a unit listed in the document entitled “Unit-Specific Ozone Season NO_x Emissions Rates for Dynamic Budget Calculations” posted at www.regulations.gov in docket EPA–HQ–OAR–2021–0668 (applicable to units located within the borders of States listed in § 52.38(b)(2)(iii)(A) through (C) of this chapter) or the document entitled “Unit-Specific Ozone Season NO_x Emissions Rates for Dynamic Budget Calculations for Five Additional States” posted at

www.regulations.gov in docket EPA–HQ–OAR–2023–0402 (applicable to units located within the borders of States listed in § 52.38(b)(2)(iii)(E) of this chapter), the NO_x emissions rate used in the calculation for the control period shall be the NO_x emissions rate shown for the unit and control period in the applicable document.

* * * * *

(c) * * *

(2) * * *

(iii) 0.11, for Arizona for the control periods in 2025 and 2026; or

(iv) 0.05, for each State for each control period in 2023 and thereafter except as otherwise specified in paragraphs (c)(2)(i) through (iii) of this section.

* * * * *

(e) * * *

(3) * * *

(i) * * *

TABLE 6 TO PARAGRAPH (e)(3)(i)—STATE-LEVEL TOTAL HEAT INPUT USED IN CALCULATIONS OF PRESET TRADING BUDGETS BY CONTROL PERIOD, 2023–2029
[mmBtu]

State	2023	2024	2025	2026	2027	2028	2029
Arizona	279,048,607	266,122,691	266,122,691	263,590,069	263,590,069		
Iowa	142,934,126	142,934,126	142,934,126	141,310,860			
Kansas	104,571,293	104,571,293	104,571,293	104,571,293			
New Mexico	82,092,237	79,168,874	79,168,874	79,168,874			
Tennessee	152,351,271	152,351,271	115,344,086	100,187,179	76,883,950		

* * * * *

■ 27. Amend § 97.1011 by revising paragraphs (b)(4)(iii)(B) and (C) to read as follows:

§ 97.1011 CSAPR NO_x Ozone Season Group 3 allowance allocations to existing units.

* * * * *

(b) * * *

(4) * * *

(iii) * * *

(B) For the control periods in 2026 and thereafter, a maximum controlled baseline under paragraph (b)(4)(iii)(A) of this section shall apply to any unit combusting any coal or solid coal-derived fuel during the historical control period for which the unit's heat input was most recently reported, serving a generator with nameplate capacity of 100 MW or more, and equipped with selective catalytic reduction controls, except a circulating fluidized bed boiler.

(C) In addition to the units described in paragraph (b)(4)(iii)(B) of this section, for the following States and control periods, a maximum controlled baseline under paragraph (b)(4)(iii)(A) of this section shall apply to any other unit located within the borders of the State, combusting any coal or solid coal-derived fuel during the historical control period for which the unit's heat input was most recently reported, and serving a generator with nameplate capacity of 100 MW or more, except a circulating fluidized bed boiler:

(1) For a State listed in § 52.38(b)(2)(iii)(A) through (C) of this chapter except Alabama, Minnesota, or Wisconsin, the control periods in 2027 and thereafter.

(2) For State listed in § 52.38(b)(2)(iii)(E) of this chapter except Iowa, Kansas, New Mexico, or Tennessee, the control periods in 2028 and thereafter.

* * * * *

■ 28. Amend § 97.1012 by revising paragraph (a) introductory text and paragraphs (a)(3)(i) and (a)(4)(ii)(B) and (C) to read as follows:

§ 97.1012 CSAPR NO_x Ozone Season Group 3 allowance allocations to new units.

(a) *Allocations from new unit set-asides.* For each control period in 2021 and thereafter and for the CSAPR NO_x Ozone Season Group 3 units in each State and areas of Indian country within the borders of the State (except, for the control periods in 2021 and 2022, areas of Indian country within the borders of the State not subject to the State's SIP authority), the Administrator will allocate CSAPR NO_x Ozone Season Group 3 allowances to the CSAPR NO_x Ozone Season Group 3 units as follows:

* * * * *

(3) * * *

(i) The first control period for which the State within whose borders the unit is located is listed in § 52.38(b)(2)(iii)(A), (B), (C), or (E) of this chapter;

* * * * *

(4) * * *

(ii) * * *

(B) For the control periods in 2024 and thereafter, a maximum controlled baseline under paragraph (a)(4)(ii)(A) of this section shall apply to any unit combusting any coal or solid coal-derived fuel during the control period, serving a generator with nameplate capacity of 100 MW or more, and equipped with selective catalytic reduction controls on or before September 30 of the preceding control period, except a circulating fluidized bed boiler.

(C) In addition to the units described in paragraph (a)(4)(ii)(B) of this section, for the following States and control periods, a maximum controlled baseline under paragraph (a)(4)(ii)(A) of this section shall apply to any other unit located within the borders of the State, combusting any coal or solid coal-derived fuel during the control period, and serving a generator with nameplate capacity of 100 MW or more, except a circulating fluidized bed boiler:

(1) For a State listed in § 52.38(b)(2)(iii)(A) through (C) of this chapter except Alabama, Minnesota, or Wisconsin, the control periods in 2027 and thereafter.

(2) For a State listed in § 52.38(b)(2)(iii)(E) of this chapter except Iowa, Kansas, New Mexico, or Tennessee, the control periods in 2028 and thereafter.

* * * * *

■ 29. Amend § 97.1021 by:

■ a. In paragraph (a), removing “period in 2021.” and adding in its place “periods in 2021 and 2022.”;

■ b. Revising paragraphs (b), (d), and (e);

■ c. In paragraph (f), removing “July 1, 2024” and adding in its place “July 1, 2026”; and

■ d. Revising paragraph (h).

The revisions read as follows:

§ 97.1021 Recordation of CSAPR NO_x Ozone Season Group 3 allowance allocations and auction results.

* * * * *

(b) By September 5, 2023, the Administrator will record in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(1) for the control periods in 2023 and 2024.

* * * * *

(d) By July 1, 2024, or, for sources located within a State listed in § 52.38(b)(2)(iii)(E) of this chapter, by [30 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], the Administrator will record in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season

Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(1) for the control period in 2025.

(e) By July 1, 2025, the Administrator will record in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(1) for the control period in 2026, unless the State in which the source is located is listed in § 52.38(b)(2)(iii)(E) of this chapter and notifies the Administrator in writing by [15 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], of the State's intent to submit to the Administrator a complete SIP revision by April 1, 2025, meeting the requirements of § 52.38(b)(10)(i) through (iv) of this chapter.

(1) If, by April 1, 2025, the State does not submit to the Administrator such complete SIP revision, the Administrator will record by July 1, 2025, in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(1) for the control period in 2026.

(2) If the State submits to the Administrator by April 1, 2025, and the Administrator approves by October 1, 2025, such complete SIP revision, the Administrator will record by October 1, 2025, in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source as provided in such approved, complete SIP revision for the control period in 2026.

(3) If the State submits to the Administrator by April 1, 2025, and the Administrator does not approve by October 1, 2025, such complete SIP revision, the Administrator will record by October 1, 2025, in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(1) for the control period in 2026.

* * * * *

(h) By July 1, 2024, or, for sources located within a State listed in § 52.38(b)(2)(iii)(E) of this chapter, by [30 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], and by July 1 of each year thereafter, the Administrator will

record in each CSAPR NO_x Ozone Season Group 3 source's compliance account the CSAPR NO_x Ozone Season Group 3 allowances allocated to the CSAPR NO_x Ozone Season Group 3 units at the source in accordance with § 97.1011(a)(2) for the control period in the year after the year of the applicable recordation deadline under this paragraph (h).

* * * * *

■ 30. Amend § 97.1024 by:

■ a. Revising paragraphs (b)(1)(ii) and (b)(3)(i) and (ii); and

■ b. In paragraph (c)(2)(ii), removing “§ 97.526(d) or § 97.826(d) or (e), in” and adding in its place “§ 97.526 or § 97.826, in”.

The revisions read as follows:

§ 97.1024 Compliance with CSAPR NO_x Ozone Season Group 3 primary emissions limitation; backstop daily NO_x emissions rate.

* * * * *

(b) * * *

(1) * * *

(ii) Two times the sum, for all CSAPR NO_x Ozone Season Group 3 units at the source to which the backstop daily NO_x emissions rate applies for the control period under paragraph (b)(3) of this section, of any excess over 50 tons for such a unit of the sum (converted to tons at a conversion factor of 2,000 lb/ton and rounded to the nearest ton), for all calendar days in the control period, of any amount by which the unit's NO_x emissions for a given calendar day in pounds exceed the product in pounds of the unit's total heat input in mmBtu for that calendar day multiplied by 0.14 lb/mmBtu; or

* * * * *

(3) * * *

(i) For the following States and control periods, the backstop daily NO_x emissions rate shall apply to any CSAPR NO_x Ozone Season Group 3 unit located within the borders of the State, combusting any coal or solid coal-derived fuel during the control period, serving a generator with nameplate capacity of 100 MW or more, and equipped with selective catalytic reduction controls on or before

September 30 of the preceding control period, except a circulating fluidized bed boiler:

(A) For a State listed in § 52.38(b)(2)(iii)(A) through (C) of this chapter, the control periods in 2024 and thereafter.

(B) For a State listed in § 52.38(b)(2)(iii)(E) of this chapter, the control periods in 2026 and thereafter.

(ii) In addition to the units described in paragraph (b)(3)(i) of this section, for each control period in 2030 and thereafter, the backstop daily NO_x emissions rate shall apply to any other CSAPR NO_x Ozone Season Group 3 unit located with the borders of a State except Alabama, Iowa, Kansas, Minnesota, New Mexico, Tennessee, or Wisconsin, combusting any coal or solid coal-derived fuel during the control period, and serving a generator with nameplate capacity of 100 MW or more, except a circulating fluidized bed boiler.

* * * * *

§ 97.1025 [Amended]

■ 31. Amend § 97.1025(c)(1) introductory text by adding “in 2024 or thereafter” after “control period”.

■ 32. Amend § 97.1026 by:

■ a. Revising paragraph (d)(2)(ii) introductory text; and

■ b. Adding paragraph (d)(2)(iii).

The revision and addition read as follows:

§ 97.1026 Banking and conversion; bank recalibration.

* * * * *

(d) * * *

(2) * * *

(ii) The CSAPR NO_x Ozone Season Group 3 allowance bank ceiling target for the control period in the year of the deadline under paragraph (d)(1) of this section, calculated as the product, rounded to the nearest allowance, of the sum for all States identified for the control period in paragraph (d)(2)(iii) of this section of the State NO_x Ozone Season Group 3 trading budgets under § 97.1010(a) for such States for such control period multiplied by—

* * * * *

(iii) The States whose trading budgets will be included in the calculation of the CSAPR NO_x Ozone Season Group 3 allowance bank ceiling target for each control period are as follows:

(A) For the control periods in 2024 and 2025, the States listed in § 52.38(b)(2)(iii)(A) through (C) of this chapter.

(B) For the control periods in 2026 and thereafter, the States listed in § 52.38(b)(2)(iii)(A) through (C) and (E) of this chapter.

* * * * *

■ 33. Amend § 97.1030 by:

■ a. In paragraph (b)(1)(iii), removing “or” after the semicolon;

■ b. In paragraph (b)(1)(iv), removing the period and adding in its place “; or”; and

■ c. Adding paragraph (b)(1)(v).

The addition reads as follows:

§ 97.1030 General monitoring, recordkeeping, and reporting requirements.

* * * * *

(b) * * *

(1) * * *

(v) May 1, 2025, for a unit in a State (and Indian country within the borders of such State) listed in § 52.38(b)(2)(iii)(E) of this chapter;

* * * * *

■ 34. Amend § 97.1034 by:

■ a. In paragraph (d)(2)(i)(B), removing “or” after the semicolon;

■ b. In paragraph (d)(2)(i)(C), adding “or” after the semicolon; and

■ c. Adding paragraph (d)(2)(i)(D).

The addition reads as follows:

§ 97.1034 Recordkeeping and reporting.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(D) The calendar quarter covering May 1, 2025, through June 30, 2025, for a unit in a State (and Indian country within the borders of such State) listed in § 52.38(b)(2)(iii)(E) of this chapter;

* * * * *

[FR Doc. 2024-01064 Filed 2-15-24; 8:45 am]

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