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Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1476; Project Identifier MCAI–2022–00508–Q; Amendment 39–22244; AD 2022–24–04]

RIN 2120–AA64

Airworthiness Directives; MarS A.S. Parachutes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–07–05, which applied to certain MarS A.S. emergency parachutes. AD 2022–07–05 superseded AD 2022–05–09, expanded the applicability, and required removing all emergency parachutes manufactured since 2016. Since the FAA issued AD 2022–07–05, MarS A.S. developed a modification for the emergency parachutes to correct the unsafe condition. This AD requires modifying and re-identifying the emergency parachutes. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 19, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 19, 2022.

The FAA must receive comments on this AD by January 17, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1476; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this final rule, contact MarS A.S., Okružní II 239, 569 43 Jevíčko, Czech Republic; phone: +420 461 353 841; email: *mars@marsjev.cz;* website: *marsjev.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–1476.

FOR FURTHER INFORMATION CONTACT: Kevin Kung, Aviation Safety Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7244; email: *9-AVS-AIR-BACO-COS@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1476; Project Identifier MCAI–2022–00508–Q'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Kevin Kung, Aviation Safety Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–07–05, Amendment 39–21992 (87 FR 15873, March 21, 2022) (AD 2022–07–05), for all MarS A.S. ATL–88/90–1B (commercially known as ATL–15 SL) emergency parachutes manufactured from 2016. AD 2022–07–05 superseded AD 2022–05–09, Amendment 39–21960 (87 FR 10712, February 25, 2022) (AD 2022–05–09) by retaining the requirement to remove the emergency parachutes from service while expanding the applicability of AD 2022–05–09 from certain serial-numbered parachutes to all emergency parachutes.

AD 2022–07–05 was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued Emergency AD 2022–0029–E, dated February 23, 2022, to correct an unsafe condition identified as the length of the ripcord between the pins being too long, which could cause a malfunction of the emergency

parachute. Malfunction of the emergency parachute could result in failure of the emergency parachute to deploy when needed.

Actions Since AD 2022–07–05 Was Issued

Since the FAA issued AD 2022–07–05, EASA revised Emergency AD 2022–0029–E, dated February 23, 2022, and issued EASA AD 2022–0029R1, dated April 11, 2022 (referred to after this as ''the MCAI''). The MCAI was issued after MarS A.S. developed a modification and re-identification of the emergency parachutes.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1476.

Comments

The FAA gave the public the opportunity to comment on AD 2022–07–05 and received comments from one commenter, the Aeronautical Repair Station Association (ARSA).

ARSA requested the FAA withdraw AD 2022–07–05 because it contends that the agency lacks the legal authority to issue an AD on MarS A.S. ATL–88/90–1B parachutes. ARSA stated that, although 14 CFR 39.3 provides that ADs may apply to an appliance, a personal parachute (such as the emergency parachute that was the subject of AD 2022–05–09 and AD 2022–07–05) is not an appliance under the definitions in 14 CFR 1.1, 91.307, or 105.3. To the extent the FAA relies upon the statutory definition of an appliance in 49 U.S.C. 40102(11), which includes a parachute, ARSA suggested that this ignores two of the three ''prerequisites'' in that definition. Specifically, ARSA stated that personal parachutes (1) are not ''used, capable of being used, or intended to be used in operating or controlling aircraft in flight'' and (2) are not ''installed in or attached to aircraft during flight.''

ARSA's position that there are three prerequisites for an item to be an appliance is based on its interpretation of the current statutory definition of ''appliance'' in 49 U.S.C. 40102(11):

> ''[A]ppliance'' means an instrument, equipment, apparatus, a part, an appurtenance, or an accessory used, capable of being used, or intended to be used, in operating or controlling aircraft in flight, including a parachute, communication equipment, and another mechanism installed in or attached to aircraft during flight, and not a part of an aircraft, aircraft engine, or propeller.

Based on the statutory history, the FAA disagrees with the commenter's interpretation. The statutory definition of appliance has included parachutes since the original Civil Aeronautics Act of 1938.[1] The definition was re-codified without change when Congress created the Federal Aviation Agency (later the Federal Aviation Administration) with the Federal Aviation Act of 1958.[2] The original versions of the statutory definition read as follows:

> 'Appliances' means instruments, equipment, apparatus, parts, appurtenances, or accessories, of whatever description, which are used, or are capable of being or intended to be used, in the navigation, operation, or control of aircraft in flight (including parachutes and including communication equipment and any other mechanism or mechanisms installed in or attached to aircraft during flight), and which are not a part or parts of aircraft, aircraft engines, or propellers.

The formatting of this original definition differs from the current definition. The original definition was changed to the current definition in 1994, when Congress revised and re-codified existing transportation and aviation legislation.[3] In the legislation's introductory text, Congress explicitly enacted the revision ''without substantive change.'' The formatting changes, therefore, did not alter the meaning of the definition. At the time of the Civil Aeronautics Act, personal use parachutes were the only type of parachute Congress could have intended to include in its definition of appliance. Whole aircraft parachutes (aircraft rescue system parachutes, airframe parachute systems, etc.) were not developed until many decades later. The FAA issues design approval for these types of parachute systems at the aircraft product level (type certificate, amended type certificate, or supplemental type certificate). As an appliance, the FAA issues design approval of personal use parachutes under a Technical Standard Order (TSO).

The FAA has been regulating parachutes—including personal use parachutes—as appliances for over 80 years. In promulgating and revising its regulations on parachute rigger certification (14 CFR part 65, subpart F) and parachute operating rules (14 CFR part 105), the agency has cited its rulemaking authority set forth in 49 U.S.C. 44701(a)(2)(A) for ''aircraft, aircraft engines, propellers, and appliances.'' [4] This is the same statutory authority for airworthiness directives under 14 CFR part 39. Moreover, the FAA's Parachute Rigger Handbook advises parachute riggers that they are required under 14 CFR part 39 to comply with parachute ADs ''to ensure the safety and function of parachutes that have been found in some manner to be defective.'' [5]

The FAA made no changes to this AD as a result of this comment.

Conclusion

The FAA reviewed the relevant data, considered the comments received on AD 2022–07–05, and determined that air safety requires adoption of the AD. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR Part 51

The FAA reviewed MarS a.s. Service Bulletin No. 01/04/2022, Rev. C, dated April 8, 2022. This service information specifies returning the affected emergency parachutes to the manufacturer for modification and re-identification. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

AD Requirements

This AD requires modifying the emergency parachutes and re-identifying part numbers (P/Ns) 09994, 09995, and 09996 as P/Ns 09994–1, 09995–1, and 09996–1, respectively. Since the modification is required as of the effective date of the AD, the parachutes cannot be used in service until they are modified.

FAA's Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA

[1] Public Law 75–706; 52 Stat. 973.

[2] Public Law 85–726; 72 Stat. 737.

[3] Act of Jan. 25, 1994, Public Law 103–272; 108 Stat. 745.

[4] See, for example, Clarification of Parachute Packing Authorization (75 FR 31283, June 3, 2010). See also Parachute Jumping (27 FR 11635, Nov. 27, 1962), in which the FAA cited Sec. 601 of the Federal Aviation Act of 1958 as its authority. Sec. 601 was later re-designated as 49 U.S.C. 44701.

[5] Parachute Rigger Handbook, FAA–H–8083–17A, Ch. 1, pp. 1–8 to 1–9 (Change 1, Dec. 2015). A copy of this document can be found at: *https://www.faa.gov/regulations_policies/handbooks_manuals/aviation.*

authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because there are no affected emergency parachutes in the United States and thus, it is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operators. Accordingly, notice and opportunity for prior public comment are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

This AD does not affect any emergency parachutes used in the United States. According to the manufacturer, none of the affected emergency parachutes were sold through its distributors in the United States. In the event an affected emergency parachute is brought into the United States, the following is an estimate of the costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modify and re-identify emergency parachute	6 work-hours × $85 per hour = $510	$88	$598	$0

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2022–07–05, Amendment 39–21992 (87 FR 15873, dated March 21, 2022); and

■ b. Adding the following new airworthiness directive:

2022–24–04 MarS A.S.: Amendment 39–22244; Docket No. FAA–2022–1476; Project Identifier MCAI–2022–00508–Q.

(a) Effective Date

This airworthiness directive (AD) is effective December 19, 2022.

(b) Affected ADs

This AD replaces AD 2022–07–05, Amendment 39–21992 (87 FR 15873, dated March 21, 2022).

(c) Applicability

This AD applies to MarS A.S. ATL–88/90–1B (commercially known as ATL–15 SL) emergency parachutes part number (P/N) 09994, P/N 09995, and P/N 09996 (no dash number) that meet either of the criterion in paragraph (c)(1) or (2) of this AD:

(1) The parachute has a date of manufacture of January 1, 2016, or later; or

(2) The date of manufacture of the parachute is unknown.

(d) Subject

Joint Aircraft System Component (JASC) Code 2563, Parachute.

(e) Unsafe Condition

This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as the length of the ripcord between the pins being too long, which could cause a malfunction of the emergency parachute. The unsafe condition, if not addressed, could result in failure of the emergency parachute to deploy when needed.

(f) Compliance

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

(g) Actions

As of the effective date of this AD, modify and re-identify each emergency parachute in accordance with the Service Bulletin Procedure, paragraph 7.b., of MarS a.s. Service Bulletin No. 01/04/2022, Rev. C, dated April 8, 2022.

(h) Special Flight Permit

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information

directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(2) of this AD and email to: *9-AVS-AIR-BACO-COS@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022–0029R1, dated April 11, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1476.

(2) For more information about this AD, contact Kevin Kung, Aviation Safety Engineer, Boston ACO Branch, Compliance & Airworthiness Division, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7244; email: *9-AVS-AIR-BACO-COS@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) MarS a.s. Service Bulletin No. 01/04/2022, Rev. C, dated April 8, 2022.

(ii) [Reserved]

(3) For service information identified in this AD, contact MarS a.s., Okružní II 239, 569 43 Jevíčko, Czech Republic; phone: +420 461 353 841; email: *mars@marsjev.cz;* website: *marsjev.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 9, 2022.

Christina Underwood,

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

[FR Doc. 2022–26206 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0881; Project Identifier MCAI–2022–00424–R; Amendment 39–22233; AD 2022–23–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Helicopters (Airbus) Model SA330J helicopters. This AD was prompted by a report of restricted movement of the collective lever caused by incidental contact of the secondary stop cover due to a loosened rivet. This AD requires removing the plate of the collective lever secondary stop and replacing it with self-adhesive tape to cover the stop support and decrease the risk of resistance on the rotor flight controls, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 6, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 6, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2022–0881; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material that is incorporated by reference (IBR) in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu;* internet *easa.europa.eu.*
- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at regulations.gov under Docket No. FAA–2022–0881.

Other Related Service Information: For Airbus service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/helicopters/services/technical-support.html.* You may also view this service information at the FAA contact information under *Material Incorporated by Reference* above.

FOR FURTHER INFORMATION CONTACT: Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0056, dated March 24, 2022 (EASA AD 2022–0056), to correct an unsafe condition for all serial-numbered Airbus (Eurocopter France, Aérospatiale, and Sud Aviation) Model SA 330 J helicopters, except those having Airbus modification (mod) 07 27362 embodied in production.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model SA330J helicopters. The NPRM published in the **Federal Register** on August 11, 2022 (87 FR 49554). The NPRM was prompted by a report of restricted movement of the collective lever during take-off. After an investigation, it was determined that the movement of the collective lever was restricted due to simultaneous movement of the collective secondary stop cover due to a loosened rivet. This investigation also determined that the loosened rivet securing the covering plate had come into contact with the collective flying control fulcrum, leading to the restricted movement of the collective lever. The NPRM proposed to require removing the plate of the collective lever secondary stop and replacing it with self-adhesive tape to cover the stop support and decrease the risk of resistance on the rotor flight controls, as specified in EASA AD 2022–0056.

The FAA is issuing this AD to address the restricted movement of the collective lever. The unsafe condition, if not addressed, could result in reduced control of the helicopter, potentially resulting in damage to the helicopter and injury to occupants. See EASA AD 2022–0056 for additional background information.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0056 requires modification of the helicopter by removing and replacing the covering plate of the collective lever secondary stop with self-adhesive tape to decrease the risk of resistance on the rotor flight controls.

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

Other Related Service Information

The FAA reviewed Airbus Alert Service Bulletin No. SA330–67.27, Revision 0, dated February 2, 2022, for Model SA330J helicopters. This service information specifies modification procedures for removal of the covering plate and installation of the self-adhesive tape.

Costs of Compliance

The FAA estimates that this AD affects 14 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Removing the covering plate of the collective lever secondary stop and replacing it with self-adhesive tape takes about 1 work-hour and parts cost up to $100 for an estimated cost of up to $185 per helicopter and $2,590 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–23–06 Airbus Helicopters: Amendment 39–22233; Docket No. FAA–2022–0881; Project Identifier MCAI–2022–00424–R.

(a) Effective Date

This airworthiness directive (AD) is effective January 6, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model SA330J helicopters, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2022–0056, dated March 24, 2022 (EASA AD 2022–0056).

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by a report of restricted movement of the collective lever caused by incidental contact of the secondary stop cover due to a loosened rivet. The FAA is issuing this AD to address the restricted movement of the collective lever. The unsafe condition, if not addressed, could result in reduced control of the helicopter, potentially resulting in damage to the helicopter and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0056.

(h) Exceptions to EASA AD 2022–0056

(1) Where EASA AD 2022–0056 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2022–0056 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information referenced in EASA AD 2022–0056 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2022–0056.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0056 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(k) Additional Information

For more information about this AD, contact Kristi Bradley, Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0056, dated March 24, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0056, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 28, 2022.

Christina Underwood,

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

[FR Doc. 2022–26175 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1070; Project Identifier MCAI–2021–00686–R; Amendment 39–22247; AD 2022–24–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) (Type Certificates Previously Held by Messerschmitt-Bolkow-Blohm (MBB), and Eurocopter Deutschland GmbH (ECD)) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding airworthiness directive (AD) 77–04–06, which applied to Messerschmitt-Bolkow-Blohm (MBB) (now Airbus Helicopters Deutschland GmbH (AHD)) Model BO–105A and BO–105 C helicopters; AD 2002–13–06, which applied to certain Eurocopter Deutschland GmbH (ECD) (now Airbus Helicopters Deutschland GmbH (AHD)) Model BO–105A, BO–105C, BO–105 C–2, BO–105 CB–2, BO–105 CB–4, BO–105 CS–2, BO–105 CBS–2, BO–105S, and BO–105LS A–1 helicopters; AD 2016–25–14, which applied to certain Airbus Helicopters Deutschland GmbH (AHD) Model BO–105LS A–3 helicopters; and AD 2021–10–14, which applied to certain Airbus Helicopters Deutschland GmbH (AHD) Model BO–105A, BO–105C, BO–105S, and BO–105LS A–3 helicopters. Since the FAA issued those ADs, new and more restrictive airworthiness limitations have been issued. This AD requires incorporating into existing maintenance records requirements (airworthiness limitations) as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also prohibits the installation of certain part-numbered tension-torsion (TT) straps. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 6, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 6, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1070; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.*
- You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–1070.

Other Related Service Information: For Airbus Helicopters service information identified in this final rule, that is not incorporated by reference, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/helicopters/services/technical-support.html.*

FOR FURTHER INFORMATION CONTACT: Kristi Bradley, COS Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 77–04–06, Amendment 39–2835 (42 FR 9670, February 17, 1977; amended 44 FR 46783, August 9, 1979) (AD 77–04–06); AD 2002–13–06, Amendment 39–12794 (67 FR 43526, June 28, 2002) (AD 2002–13–06); AD 2016–25–14, Amendment 39–18740 (81 FR 94944, December 27, 2016) (AD 2016–25–14); and AD 2021–10–14, Amendment 39–21547 (86 FR 27268, May 20, 2021) (AD 2021–10–14).

AD 77–04–06 applied to Messerschmitt-Bolkow-Blohm (MBB) Model BO–105A and BO–105C helicopters. AD 77–04–06 was prompted by reports of internal corrosion of the main rotor gearbox (MGB) supports, which could significantly reduce the structural strength and service life. After AD 77–

04–06 was issued, the FAA determined based on service experience and additional test investigations the total hours time-in-service (TIS) for certain part-numbered MGB supports could be increased. Accordingly, the FAA amended AD 77–04–06 by issuing Amendment 39–3528 (44 FR 46783, August 9, 1979), which increased the life limit for the MGB supports.

AD 2002–13–06 applied to Eurocopter Deutschland GmbH (ECD) Model BO–105A, BO–105C, BO–105 C–2, BO–105 CB–2, BO–105 CB–4, BO–105S, BO–105 CS–2, BO–105 CBS–2, BO–105 CBS–4, and BO–105LS A–1 helicopters, with certain part-numbered main rotor (MR) head assemblies and certain part-numbered TT straps installed. AD 2002–13–06 was prompted by an accident in which an MR blade separated from a Eurocopter Model MBB–BK 117 helicopter due to fatigue failure of a TT strap; the same part-numbered TT strap is used on Model BO–105 helicopters. AD 2002–13–06 was also prompted by the determination that an additional life limit for certain part-numbered TT straps needed to be established. AD 2002–13–06 required creating a component log card or equivalent record and determining the calendar age, number of flights, and flight hours TIS on certain part-numbered TT straps; removing and replacing certain TT straps, and modifying certain MR heads before certain part-numbered TT straps are installed. AD 2002–13–06 also required revising the Airworthiness Limitations Schedule (ALS) of the existing maintenance manual to reflect the new life limits.

AD 2016–25–14 applied to Airbus Helicopters Deutschland GmbH (AHD) Model BO–105LS A–3 helicopters with certain part-numbered TT straps installed. AD 2016–25–14 was prompted by the determination that life limits have been introduced for certain part-numbered TT straps installed on the helicopter lifting system, and during the revision of the ALS for the existing Model BO–105LS A–3 maintenance manual, the life limit for the TT strap was inadvertently deleted. AD 2016–25–14 required inspecting the helicopter records to determine the life limit of the TT straps. Depending on the results, AD 2016–25–14 required establishing a life limit if none exists; revising the ALS of the existing maintenance manual, and creating a component history card or equivalent record to reflect this life limit; and replacing certain TT straps.

AD 2021–10–14 applied to Airbus Helicopters Deutschland GmbH (AHD) Model BO–105A, BO–105C, BO–105S, and BO105LS A–3 helicopters equipped with a certain TT strap. AD 2021–10–14 was prompted by the FAA's determination that aging of the elastomeric material in a TT strap could affect the structural characteristics of the TT strap. AD 2021–10–14 required replacement of certain TT straps with serviceable parts and implementation of a new storage life limit for TT straps.

The NPRM published in the **Federal Register** on September 7, 2022 (87 FR 54636). The NPRM was prompted by EASA AD 2021–0142, dated June 17, 2021 (EASA AD 2021–0142), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD), formerly Eurocopter Deutschland GmbH, Eurocopter Hubschrauber Deutschland GmbH, Messerschmitt-Bölkow-Blohm GmbH; Eurocopter Canada Ltd, formerly Messerschmitt-Bölkow-Blohm Helicopter Canada Limited, Model BO105 A, BO105 C, BO105 D, BO105 S, BO105 LS A–1, and BO105 LS A–3 helicopters, all variants, all serial numbers, including BO105 LS A–3 helicopters modified in accordance with EASA Supplemental Type Certificate (STC) 10039633, or previously Luftfahrt-Bundesamt (LBA) Germany STC EMZ NR. 0654/3058 (commercially known as ''Superlifter''). EASA AD 2021–0142 superseded a series of ADs to include EASA AD 2019–0024, dated February 4, 2019 (which prompted AD 2021–10–14); EASA AD 2015–0042, dated March 9, 2015 (which prompted AD 2016–25–14); EASA AD 2013–0015, dated January 16, 2013; EASA AD 2010–0153, dated July 27, 2010; LBA Germany AD 2001–281, dated October 18, 2001 (which prompted AD 2002–13–06); and LBA Germany AD 76–136/2, dated October 5, 1978 (which prompted AD 77–04–06).

The NPRM proposed to require incorporating into existing maintenance records new and more restrictive requirements (airworthiness limitations), as specified in EASA AD 2021–0142. The NPRM also proposed to prohibit the installation of certain part-numbered TT straps. The FAA is issuing this AD to address the unsafe condition on these products.

Additionally, the actions required to address the unsafe conditions in AD 77–04–06, AD 2002–13–06, AD 2016–25–14, and AD 2021–10–14 are included in ''the applicable ALS,'' as defined in EASA AD 2021–0142. Therefore, the FAA is superseding AD 77–04–06, AD 2002–13–06, AD 2016–25–14, and AD 2021–10–14 in order to reduce the burden on operators by requiring compliance with a single FAA AD in lieu of multiple FAA ADs.

You may examine EASA AD 2021–0142 in the AD docket at regulations.gov under Docket No. FAA–2022–1070.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments regarding the NPRM or on the determination of the cost to the public.

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0142 requires replacing certain components before exceeding their applicable life limit. EASA AD 2021–0142 also prohibits installing Bendix TT-strap part number 2602559, 2606576, 2604067, or 117–14110, and requires revising the approved aircraft maintenance program (AMP) by incorporating the limitations described in ''the applicable ALS'' as defined in EASA AD 2021–0142.

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

Other Related Service Information

The FAA reviewed Airbus Helicopters BO 105 Maintenance Manual (MM), Revision 31, dated December 15, 2020, for Model BO–105A, BO–105C, BO–105 D, BO–105S, and BO–105LS A–1 helicopters; Airbus Helicopters BO 105 LS A–3 MM, Revision 7, dated November 27, 2018, for Model BO–105 LS A–3 helicopters; and Airbus Helicopters MM BO 105 LS A–3 ''Super Lifter'' Appendix 010, Revision 4, dated March 28, 2019, for BO 105 LS A–3 ''Superlifter'' helicopters.

This service information specifies certain actions and associated thresholds and intervals, including life limits and maintenance tasks. These requirements (airworthiness limitations) include new life limits, including cure dates and storage life limits, for certain part-numbered TT straps.

ADs Mandating Airworthiness Limitations

The FAA has previously mandated airworthiness limitations by mandating each airworthiness limitation task (*e.g.,* inspections and replacements (life limits)) as an AD requirement or issuing ADs that require revising the ALS of the existing maintenance manual or instructions for continued airworthiness to incorporate new or revised inspections and life limits. This AD, however, requires operators to incorporate into maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2), as applicable for your helicopter, the requirements (airworthiness limitations) specified in EASA AD 2021–0142. The FAA does not intend this as a substantive change. For these ADs, the ALS requirements for operators are the same but are complied with differently. Requiring the incorporation of the new ALS requirements into the maintenance records, rather than requiring individual ALS tasks (*e.g.,* repetitive inspections and replacements), requires operators to record AD compliance once after updating the maintenance records, rather than after every time the ALS task is completed.

In addition, paragraph (h) of this AD allows operators to incorporate later approved revisions of the ALS document as specified in the ''Ref. Publications'' section of EASA AD 2021–0142 without the need for an alternative method of compliance (AMOC).

Differences Between This AD and the EASA AD

This AD does not require compliance with paragraphs (3), (4), and (5) of EASA AD 2021–0142.

EASA AD 2021–0142 is applicable to Model BO–105D helicopters, whereas this AD is not because Model BO–105D helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet. EASA AD 2021–0142 is applicable to Model BO–105 LS A–3 helicopters modified in accordance with EASA STC 10039633, or previously LBA Germany STC EMZ NR. 0654/3058 (commercially known as ''Superlifter''), whereas this AD applies to Model BO–105 LS A–3 helicopters modified in accordance with STC SR00043RD.

Costs of Compliance

The FAA estimates that this AD affects 67 helicopters of U.S. registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Incorporating requirements (airworthiness limitations) into existing maintenance records takes about 2 work-hours for an estimated cost of $170 per helicopter and $11,390 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 77–04–06, Amendment 39–2835 (42 FR 9670, February 17, 1977; amended 44 FR 46783, August 9, 1979); Airworthiness Directive 2002–13–06, Amendment 39–12794 (67 FR 43526, June 28, 2002); Airworthiness Directive 2016–25–14, Amendment 39–18740 (81 FR 94944, December 27, 2016); and Airworthiness Directive 2021–10–14, Amendment 39–21547 (86 FR 27268, May 20, 2021); and

■ b. Adding the following new airworthiness directive:

2022–24–07 Airbus Helicopters Deutschland GmbH (AHD) (Type Certificates previously held by Messerschmitt-Bolkow-Blohm (MBB), and Eurocopter Deutschland GmbH (ECD)): Amendment 39–22247; Docket No. FAA–2022–1070; Project Identifier MCAI–2021–00686–R.

(a) Effective Date

This airworthiness directive (AD) is effective January 6, 2023.

(b) Affected ADs

This AD replaces the ADs specified in paragraphs (b)(1) through (4) of this AD.

(1) AD 77–04–06, Amendment 39–2835 (42 FR 9670, February 17, 1977; amended 44 FR 46783, August 9, 1979).

(2) AD 2002–13–06, Amendment 39–12794 (67 FR 43526, June 28, 2002).

(3) AD 2016–25–14, Amendment 39–18740 (81 FR 94944, December 27, 2016).

(4) AD 2021–10–14, Amendment 39–21547 (86 FR 27268, May 20, 2021).

Note 1 to paragraph (b): The requirements of this AD capture the latest tasks and life limits required to prevent the unsafe conditions addressed by the ADs that are identified in paragraphs (b)(1) through (4) of this AD.

(c) Applicability

This AD applies to all Airbus Helicopters Deutschland GmbH (AHD) (type certificates previously held by Messerschmitt-Bolkow-Blohm (MBB), and Eurocopter Deutschland GmbH (ECD)) Model BO–105A, BO–105C, BO–105S, BO–105LS A–1, and BO–105LS A–3 helicopters, including BO–105LS A–3 helicopters modified in accordance with Supplemental Type Certificate SR00043RD, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6300, Main Rotor Drive System.

(e) Unsafe Condition

This AD was prompted by new and more restrictive airworthiness limitations. The FAA is issuing this AD to address the failure of certain parts, which could result in the loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 30 days after the effective date of this AD, incorporate into maintenance records required by 14 CFR 91.417(a)(2) or 135.439(a)(2), as applicable for your model and configuration helicopter, the requirements (airworthiness limitations) specified in paragraphs (1.1), (1.2), and (1.3), and the Definitions section, of European Union Aviation Safety Agency (EASA) AD 2021–0142, dated June 17, 2021 (EASA AD 2021–0142). Where paragraphs (1.2) and (1.3) of EASA AD 2021–0142 refer to its effective date, this AD requires using the effective date of this AD.

(2) As of the effective date of this AD, comply with the parts installation prohibition specified in paragraph (2) of EASA AD 2021–0142.

(h) Provisions for Alternative Requirements (Airworthiness Limitations)

After the actions required by paragraph (g)(1) of this AD have been done, no alternative requirements (airworthiness limitations) are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0142.

(i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are prohibited.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(k) Related Information

For more information about this AD, contact Kristi Bradley, COS Program Manager, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5110; email *kristin.bradley@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2021–0142, dated June 17, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0142, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu,* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 10, 2022.

Christina Underwood,

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

[FR Doc. 2022–26253 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1158; Project Identifier MCAI–2022–00771–E; Amendment 39–22246; AD 2022–24–06]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) BR700–710A1–10, BR700–710A2–20, and BR700–710C4–11 model turbofan engines. This AD was prompted by reports of cracks on certain low-pressure compressor (LPC) rotor (fan) disks. This AD requires initial and repetitive visual inspections of certain LPC rotor fan disks and, depending on the results of the inspections, replacement of any LPC rotor fan disk with cracks detected. This AD also allows modification of the engine in accordance with RRD service information as a terminating action to these inspections, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference (IBR). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 6, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 6, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1158; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–1158.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain RRD BR700–710A1–10, BR700–710A2–20, and BR700–710C4–11 model turbofan engines. The NPRM published in the **Federal Register** on September 14, 2022 (87 FR 56284). The NPRM was prompted by EASA AD 2022–0110, dated June 15, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (referred to after this as ''the MCAI''). The MCAI states that there

have been reports of cracks on certain LPC rotor fan disks.

In the NPRM, the FAA proposed to require accomplishing the actions specified in EASA AD 2022–0110, described previously, except for any differences or exceptions identified in the NPRM. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022–0110. EASA AD 2022–0110 specifies procedures for initial and repetitive visual inspections of certain LPC rotor fan disks, and replacement of any LPC rotor fan disk with cracks detected.

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

Other Related Service Information

The FAA reviewed RRD BR700 Series Propulsion System Service Bulletin (SB) SB–BR700–72–101474, Revision 1, dated November 18, 2014 (RRD BR700 Series Propulsion System SB SB–BR700–72–101474); RRD BR700 Series Propulsion System SB SB–BR700–72–101952, Initial Issue, dated December 1, 2016 (RRD BR700 Series Propulsion System SB SB–BR700–72–101952); and RRD BR700 Series Propulsion System SB SB–BR700–72–A900732, Initial Issue, dated June 7, 2022 (RRD BR700 Series Propulsion System SB SB–BR700–72–A900732).

RRD BR700 Series Propulsion System SB–BR700–72–101474 and RRD BR700 Series Propulsion System SB SB–BR700–72–101952 describe procedures for the modification of the engine as a terminating action to the initial and repetitive visual inspections of certain LPC rotor fan disks. RRD BR700 Series Propulsion System SB SB–BR700–72–A900732 specifies procedures for initial and repetitive visual inspections of certain LPC rotor fan disks.

Costs of Compliance

The FAA estimates that this AD affects 2,068 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect LPC compressor rotor fan disk	4 work-hours × $85 per hour = $340	$0	$340	$703,120

The FAA estimates the following costs to do any necessary replacements that are required based on the results of the inspection. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace LPC compressor rotor fan disk	10 work-hours × $85 per hour = $850	$470,000	$470,850

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–24–06 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Amendment 39–22246; Docket No. FAA–2022–1158; Project Identifier MCAI–2022–00771–E.

(a) Effective Date

This airworthiness directive (AD) is effective January 6, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) BR700–710A1–10, BR700–710A2–20, and BR700–710C4–11 model turbofan engines as identified in European Union Aviation Safety Agency AD 2022–0110, dated June 15, 2022 (EASA AD 2022–0110).

(d) Subject

Joint Aircraft Service Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by reports of cracks on certain low-pressure compressor (LPC) rotor (fan) disks. The FAA is issuing this AD to prevent failure of the LPC rotor fan or blade. The unsafe condition, if not addressed, could result in high energy debris release, damage to the airplane, and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, EASA AD 2022–0110.

(h) Exceptions to EASA AD 2022–0110

(1) Where EASA AD 2022–0110 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2022–0110 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0110 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency AD 2022–0110, dated June 15, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0110, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 14, 2022.

Christina Underwood,

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

[FR Doc. 2022–26274 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0015; Project Identifier AD–2021–00832–R; Amendment 39–22252; AD 2022–24–12]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–23–05 for certain Airbus Helicopters Model EC225LP helicopters. AD 2020–23–05 required inspecting the control rod attachment yokes (yokes) of certain main rotor (M/R) rotating swashplates (swashplates), establishing a life limit, performing a one-time inspection of stripped yokes, and applicable corrective actions. Since the FAA issued AD 2020–23–05, the FAA has determined that certain swashplates are not susceptible to the unsafe condition, repetitive inspections for certain swashplates are necessary, and the criteria for when to perform a dye penetrant inspection needed to be revised. This AD retains some of the requirements of AD 2020–23–05 and also requires compliance with a revised life limit; performing a repetitive visual inspection of the yokes on certain swashplates; and depending on the inspection results, removing the affected swashplates from service, performing a dye penetrant inspection of the yoke, and additional corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 6, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 6, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–0015; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/helicopters/technical-services/support.html.*
- You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy. Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2022–0015.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; phone: (202) 267–9167; email: *hal.jensen@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020) (AD 2020–23–05). AD 2020–23–05 applied to Airbus Helicopters Model EC225LP helicopters with a swashplate part number (P/N) 332A31–3074–00 or P/N 332A31–3074–01 installed. AD 2020–23–05 required inspecting the yokes of certain swashplates, establishing a life limit, performing a one-time inspection of stripped yokes, and applicable corrective actions. The FAA issued AD 2020–23–05 to detect a crack in a swashplate yoke, which could result in failure of the yoke, loss of M/R control, and subsequent loss of control of the helicopter. The NPRM published in the **Federal Register** on January 26, 2022 (87 FR 3943). The NPRM was prompted by determinations following the issuance of AD 2020–23–05 and EASA AD 2019–0074, dated March 28, 2019 (EASA AD 2019–0074), and issued by EASA, which is the Technical Agent for the Member States of the European Union. EASA AD 2019–0074 stated that Airbus Helicopters established a life limit (also called a service life limit) of 12 years for the swashplate and added a reporting requirement if there is a crack or corrosion in a yoke. EASA further advised that additional analysis determined that it is necessary to introduce a new life limit for affected swashplates.

You may examine EASA AD 2019–0074 in the AD docket at *regulations.gov* under Docket No. FAA 2022–0015.

In the NPRM, the FAA proposed to continue to require all of the requirements of AD 2020–23–05 and also proposed to require a revised compliance time for the initial visual inspection of the yokes on certain swashplates and clarify that dye penetrant inspection of the yoke is required before further flight if no cracks are detected during the visual inspection.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 to supersede AD 2020–23–05. The SNPRM published in the **Federal Register** on July 29, 2022 (87 FR 45715). The SNPRM was prompted by EASA AD 2019–0074R1, dated March 8, 2022 (EASA AD 2019–0074R1), which revised EASA AD 2019–0074.

In the SNPRM, the FAA proposed to continue to require some of the requirements of AD 2020–23–05 and also proposed to require compliance with a revised life limit; performing a repetitive visual inspection of the yokes on swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture; and if a crack is detected, removing the swashplate from service. If no cracks are detected as a result of a visual inspection but a scratch or surface degradation is detected, the SNPRM proposed to require performing a dye penetrant inspection of the yoke. If a crack is detected during the dye penetrant inspection, the SNPRM proposed to require removing the swashplate from service.

Since the NPRM was issued, the FAA determined that swashplates that have accumulated less than 7 years since the date of manufacture are not susceptible to the unsafe condition. The FAA also determined that repetitive inspections for swashplates that have accumulated 7 or more years, but less than 13 years, since the date of manufacture are necessary and the criteria for when to perform a dye penetrant inspection needed to be revised. In light of this, the FAA revised the SNPRM accordingly.

In the SNPRM, the FAA also corrected the description of what prompted AD 2020–23–05, updated the related service information that was proposed for incorporation by reference to the current revision, and updated the estimated number of work-hours for inspecting the yokes in the Costs of Compliance section.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. Except for minor editorial changes, this AD is adopted as proposed in the SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed one document that co-publishes two Airbus Helicopters Emergency Alert Service Bulletin (EASB) identification numbers: EASB No. 05A051 for Model EC225LP helicopters (EASB 05A051 Rev 4), and EASB No. 05A046 for non-FAA type-certificated Model EC725AP helicopters (EASB 05A046 Rev 4), both Revision 4, and both dated February 28, 2022. EASB 05A051 Rev 4 is incorporated by reference in this AD; EASB 05A046 Rev 4 is not.

This service information specifies inspections for swashplate P/N 332A31–3074–00 and P/N 332A31–3074–01. This service information specifies procedures for a repetitive inspection of the yokes for a crack and a one-time inspection of the stripped yokes for corrosion and a crack. If in doubt about whether there is a crack, this service information specifies performing a nondestructive inspection.

Additionally, this service information specifies touching up the swashplate with varnish if there is corrosion, removing any damage within allowable limits, and refinishing the yokes. If there is a crack in a yoke, this service information specifies replacing the swashplate. This service information also specifies a life limit of 13 years since the date of manufacture for the swashplates and reporting requirements if a crack or corrosion is discovered. EASB 05A051 Rev 4 also updates the list of serial numbers and manufacture dates of the swashplates.

This service information is reasonably available because the interested parties have access to it through their normal

course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and EASA AD 2019–0074R1 or the Service Information

EASB 05A051 Rev 4 specifies performing a non-destructive inspection if in doubt about whether there is a crack in a yoke. This AD requires a visual inspection and if no cracks are detected, visually inspecting for a scratch and surface degradation. If a scratch or surface degradation is detected, this AD requires a non-destructive inspection (dye penetrant inspection). EASB 05A051 Rev 4 also specifies sending the swashplate back to Airbus Helicopters if cracks are found, whereas this AD does not require sending any affected parts back to Airbus Helicopters.

EASA AD 2019–0074R1 requires reporting inspection results, whereas this AD does not require reporting inspection results.

Costs of Compliance

The FAA estimates that this AD affects 28 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determination of the manufacture date of the swashplate.	0.5 work-hour × $85 per hour = $43.	$0	$43	$1,204.
Inspecting the yokes	0.5 work-hour × $85 per hour = $43 per inspection cycle.	0	$43 per inspection cycle.	$1,204 per inspection cycle.
Removing grease, stripping the yokes, and inspecting the stripped yokes.	8 work-hours × $85 per hour = $680.	0	$680	$19,040.
Creating a life limit record	1 work-hour × $85 per hour = $85	0	$85	$2,380.

The FAA estimates the following costs to do any necessary on-condition actions that are required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Removing any corrosion or repairing damage within the allowable limit.	3 work-hours × $85 per hour = $255	$0	$255
Replacing the swashplate	6 work-hours × $85 per hour = $510	85,661	86,171
Dye-penetrant inspection	6 work-hours × $85 per hour = $510	50	560

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020); and

■ b. Adding the following new airworthiness directive:

2022–24–12 Airbus Helicopters: Amendment 39–22252; Docket No. FAA–2022–0015; Project Identifier AD–2021–00832–R.

(a) Effective Date

This airworthiness directive (AD) is effective January 6, 2023.

(b) Affected ADs

This AD replaces AD 2020–23–05, Amendment 39–21321 (85 FR 73604, November 19, 2020).

(c) Applicability

This AD applies to Airbus Helicopters Model EC225LP helicopters, certificated in any category, with a main rotor (M/R) rotating swashplate (swashplate) part number (P/N) 332A31–3074–00 or P/N 332A31–3074–01 installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6230, Main Rotor Mast/Swashplate.

(e) Unsafe Condition

This AD was prompted by results of testing, which determined that a crack could develop in a swashplate control rod attachment yoke (yoke), and the notification of a new life limit for certain swashplates. The FAA is issuing this AD to detect and correct a crack in a yoke. The unsafe condition, if not addressed, could result in failure of the yoke, loss of M/R control, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Before further flight, review Appendix 4.A. of Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05A051, Revision 4, dated February 28, 2022 (EASB 05A051 Rev 4) to determine the date of manufacture of the swashplate.

(1) If the swashplate has accumulated 13 or more years since the date of manufacture, remove the swashplate from service.

(2) If the swashplate has accumulated less than 13 years since the date of manufacture, create a component history card or equivalent record indicating a life limit of 13 years since the date of manufacture. Thereafter, continue to record the life limit of the swashplate on its component history card or equivalent record and remove any swashplate from service before accumulating 13 years since the date of manufacture.

(3) For each swashplate that has accumulated 7 or more years, but less than 13 years, since the date of manufacture, within 15 hours time-in-service (TIS) or 7 days, whichever occurs first after the effective date of this AD, and thereafter at intervals not to exceed 15 hours TIS or 7 days, whichever occurs first, until the swashplate accumulates 13 years since the date of manufacture, visually inspect each yoke for a crack, paying particular attention to the areas shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. If there is any crack on the yoke, before further flight, remove the swashplate from service.

(i) If no cracks are visually detected, before further flight, visually inspect for a scratch and surface degradation on the yoke.

(ii) If there is any scratch or surface degradation on the yoke, before further flight, perform a dye penetrant inspection of the yoke for a crack.

(iii) If there is any crack on the yoke, before further flight, remove the swashplate from service.

(4) For each swashplate that has accumulated 7 or more years, but less than 13 years, since the date of manufacture, within 100 hours TIS after the effective date of this AD:

(i) Remove the grease from areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. Using a plastic spatula, strip areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4. Do not use a metal tool to strip any area of a yoke.

(ii) Inspect areas (E), (F), (G), (H), (J), and (K) of each yoke as shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4 for corrosion, pitting, and loss of material.

(A) If there is any corrosion less than 0.0078 in. (0.2 mm), before further flight, remove the corrosion and apply varnish (Vernelec 43022 or equivalent) to the surface of areas (E), (F), (G), (H), (J), and (K).

(B) If there is any pitting or loss of material of less than 0.0078 in. (0.2 mm), before further flight, remove the damage by sanding with sandpaper 200/400 or 330.

(C) If there is any corrosion, pitting, or loss of material of 0.0078 in. (0.2 mm) or greater, before further flight, remove the swashplate from service.

(iii) Visually inspect each yoke for a crack, paying particular attention to the areas shown in Details B, C, and D of Figure 1 of EASB 05A051 Rev 4.

(A) If there is any crack on the yoke, before further flight, remove the swashplate from service.

(B) If no cracks are visually detected, before further flight, perform the actions as required in paragraphs (g)(3)(i) through (iii) of this AD.

(h) Credit for Previous Actions

If you performed the actions in paragraph (g)(4) of this AD before the effective date of this AD using Airbus Helicopters EASB No. 05A051, Revision 1, dated November 16, 2017; Airbus Helicopters EASB No. 05A051, Revision 2, dated February 26, 2019; or Airbus Helicopters EASB No. 05A051 Revision 3, dated December 7, 2021, you have met the requirements of paragraph (g)(4) of this AD.

(i) Special Flight Permits

Special flight permits are prohibited.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(k) Related Information

(1) For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; phone: (202) 267–9167; email: *hal.jensen@faa.gov.*

(2) Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05A051, Revision 1, dated November 16, 2017; Airbus Helicopters EASB No. 05A051, Revision 2, dated February 26, 2019; and Airbus Helicopters EASB No. 05A051 Revision 3, dated December 7, 2021, which are not incorporated by reference, contain additional information about the subject of this AD. This service information is available at the contact information specified in paragraphs (l)(3) and (4) of this AD.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2019–0074R1, dated March 8, 2022. You may view the EASA AD at *regulations.gov* under Docket No. FAA–2022–0015.

(l) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Emergency Alert Service Bulletin No. 05A051, Revision 4, dated February 28, 2022.

Note 1 to paragraph (l)(2)(i): Airbus Helicopters Emergency Alert Service Bulletin No. 05A051, Revision 4, dated February 28, 2022, is co-published as one document along with Airbus Helicopters Emergency Alert Service Bulletin No. 05A046, Revision 4, dated February 28, 2022, which is not incorporated by reference in this AD.

(ii) [Reserved]

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/helicopters/services/technical-support.html.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 16, 2022.

Christina Underwood,

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

[FR Doc. 2022–26219 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1073; Airspace Docket No. 22–AEA–13]

RIN 2120–AA66

Amendment of Class E Airspace; Oneonta, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace extending upward from 700 feet above the surface at Albert S. Nader Regional Airport, Oneonta, NY, by updating the airport's name and removing the Rockdale VORTAC from the Class E airspace description, as well as amending the radius, and removing an extension. Also, this action updates the airport's geographic coordinates. This action enhances the safety and management of controlled airspace within the national airspace system.

DATES: Effective 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace for Albert S. Nader Regional Airport, Oneonta, NY, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 52864, August 30, 2022) for Docket No. FAA–2022–1073 to amend Class E airspace extending upward from 700 feet above the surface at Albert S. Nader Regional Airport, Oneonta, NY. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by amending Class E airspace extending upward from 700 feet above the surface for Albert S. Nader Regional Airport (formerly Oneonta Municipal Airport), Oneonta, NY, by updating the airport name and geographic coordinates to coincide with the FAA's database. Also, an airspace evaluation resulted in an increase of the Class E airspace radius to 6.7-miles (previously 6.5-miles) and the removal of the southwest extension. The Rockdale VORTAC is removed from the airspace description, as it is unnecessary in describing the airspace. This action enhances the safety and management of controlled airspace within the national airspace system.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraphs 5–6.5a.

This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11G,

Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA NY E5 Oneonta, NY [Amended]

Albert S. Nader Regional Airport, NY
(Lat. 42°31′29″ N, long. 75°03′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Albert S. Nader Regional Airport.

Issued in College Park, Georgia, on November 28, 2022.

Lisa E. Burrows,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–26148 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1447; Airspace Docket No. 22–AEA–35]

RIN 2120–AA66

Amendment of Class D Airspace; Fort Belvoir, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D airspace at Davison Army Airfield (AAF), Fort Belvoir, VA. The geographic coordinates of the airfield and the Outer Marker are being updated to coincide with the FAA's aeronautical database. In addition, this action makes the editorial changes replacing the term Notice to Airmen with Notice to Air Missions and replacing the term Airport/Facility Directory with Chart Supplement. This action does not change the airspace boundaries or operating requirements.

DATES: Effective 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Goodson, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–5966.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it amends airspace in Fort Belvoir, VA, to support IFR operations in the area. This update is administrative change and does not change the airspace boundaries or operating requirements.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class D airspace at Davison AAF, Fort Belvoir, VA, by updating the geographic coordinates of the airport and the Outer Marker to coincide with the FAA's aeronautical database. In addition, this action makes the editorial changes replacing the term Notice to Airmen with Notice to Air Missions and replacing the term Airport/Facility Directory with Chart Supplement.

This action is an administrative change and does not affect the airspace boundaries or operating requirements; therefore, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and is unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AEA VA D Fort Belvoir, VA [Amended]

Davison AAF, Fort Belvoir, VA
(Lat. 38°42′54″ N, long. 77°10′51″ W)
DAVEE OM
(Lat. 38°39′42″ N, long. 77°06′36″ W)

That airspace extending upward from the surface to but not including 2,500 feet MSL within a 4.4- mile radius of Davison AAF and within 1 mile each side of the Davison AAF localizer southeast course extending from the 4.4-mile radius to the DAVEE OM and within 1.8 miles each side of the extended centerline of Runway 14/32 extending from the northwest end of Runway 14/32 to 4.4 miles northwest, excluding the portion within Prohibited Area P–73 and the Washington Tri-Area Class B airspace area. This Class D airspace area is effective during specific times and dates established in advance by a Notice to Air Missions. The specific date and time will thereafter be published continuously in the Chart Supplement.

Issued in College Park, Georgia, on November 28, 2022.

Lisa Burrows,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–26150 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0110; Airspace Docket No. 22–AAL–7]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 26 (B–26); Fort Yukon, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Blue 26 (B–26) in the vicinity of Fort Yukon, AK, due to the planned decommissioning of the Yukon River, AK (FTO), Non-Directional Beacon (NDB).

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0110 in the **Federal Register** (87 FR 11657; March 2, 2022), revoking Colored Federal airway B–26 in the vicinity of Fort Yukon, AK, due to the planned decommissioning of the Yukon River, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Blue Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway B–26 in the vicinity of Fort Yukon, AK, due to the planned decommissioning of the Yukon River, AK, NDB. The amendment is described below.

B–26: B–26 extends between the Chena, AK, NDB and the Yukon River, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway B–26, due to the planned decommissioning of the Fort Yukon, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially

change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(d) Blue Federal Airways.

* * * * *

B–26 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26163 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0165; Airspace Docket No. 22–AAL–14]

RIN 2120–AA66

Revocation of Colored Federal Airway Green 18 (G–18); Point Lay, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Green 18 (G–18) due to the planned decommissioning of the Point Lay, AK (PIZ), Non-Directional Beacon (NDB).

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0165 in the **Federal Register** (87 FR 12901; March 8, 2022), revoking Colored Federal airway G–18 due to the planned decommissioning of the Point Lay, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Green Federal airways are published in paragraph 6009(a) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway G–18 due to the planned decommissioning of the Point Lay, AK, NDB in the vicinity of Point Lay, AK. The amendment is described below.

G–18: G–18 extends between the Hotham, AK, NDB and the Atqasuk, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is

certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway G–18, due to the planned decommissioning of the Point Lay, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(a) Green Federal Airways.

* * * * *

G–18 [Removed]

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26165 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0172; Airspace Docket No. 22–AAL–3]

RIN 2120–AA66

Revocation of Colored Federal Airways Amber 5 (A–5) and Blue 4 (B–4); Bettles, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airways Amber 5 (A–5) and Blue 4 (B–4) in the vicinity of Bettles, AK, due to the planned decommissioning of the Evansville, AK (EAV), Non-Directional Beacon (NDB).

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0172 in the **Federal Register** (87 FR 13665; March 10, 2022), revoking Colored Federal airways A–5 and B–4 due to the planned decommissioning of the Evansville, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Amber Federal airways are published in paragraph 6009(c) and Blue Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airways listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airways A–5 and B–4 due to the planned

decommissioning of the Evansville, AK, NDB. The airway amendments are described below.

A–5: A–5 extends between the Ambler, AK, NDB and the Evansville, AK, NDB. The airway is removed in its entirety.

B–4: B–4 extends between the Utopia Creek, AK, NDB and the Yukon River, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airways A–5 and B–4, due to the planned decommissioning of the Evansville, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(c) Amber Federal Airways.

* * * * *

A–5 [Removed]

* * * * *

Paragraph 6009(d) Blue Federal Airways.

* * * * *

B–4 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26162 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0312; Airspace Docket No. 22–AAL–20]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 37 (B–37); Level Island, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Blue 37 (B–37) due to the planned decommissioning of the Sumner Strait, AK (SQM), Non-Directional Beacon (NDB) in the vicinity of Level Island, AK.

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic

within the National Airspace System (NAS).

Background

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0311 in the **Federal Register** (87 FR 19409; April 4, 2022), revoking Colored Federal airway B–37 due to the planned decommissioning of the Sumner Strait, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Blue Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Differences From the NPRM

Subsequent to the NPRM, the FAA identified an inadvertent typographical error that listed the Docket No. as FAA–2022–0311 in error. The correct Docket No. for this rulemaking is FAA–2022–0312. This action corrects the Docket No. typographical error to reflect it as FAA–2022–0312.

The rulemaking action to revoke B–37 is unaffected by this administrative error correction.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway B–37 due to the planned decommissioning of the Sumner Strait, AK, NDB in the vicinity of Level Island, AK. The amendment is described below.

B–37: B–37 extends between the Sumner Strait, AK, NDB and the intersection of the Elephant, AK, NDB 272° and the Ocean Cape, AK, NDB 139° bearings (SPARL Fix). The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway B–37, due to the planned decommissioning of the Sumner Strait, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. §§ 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(d) Blue Federal Airways.

* * * * *

B–37 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26169 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0120; Airspace Docket No. 22–AAL–15]

RIN 2120–AA66

Revocation of Colored Federal Airway Red 51 (R–51); Level Island, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Red 51 (R–51) due to the planned decommissioning of the Sumner Strait, AK (SQM), Non-Directional Beacon (NDB).

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under

1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0120 in the **Federal Register** (87 FR 14192; March 14, 2022), revoking Colored Federal airway R–51 due to the planned decommissioning of the Sumner Strait, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Red Federal airways are published in paragraph 6009(b) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway R–51 due to the planned decommissioning of Sumner Strait, AK, NDB in the vicinity of Level Island, AK.

R–51: R–51 extends between the Sumner Strait, AK, NDB and the Sitka, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway R–51, due to the planned decommissioning of the Sumner Strait, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(b) Red Federal Airways.

* * * * *

R–51 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26166 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0539; Airspace Docket No. 22–AAL–13]

RIN 2120–AA66

Revocation of Colored Federal Airway Green 17 (G–17); Atqasuk, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Green 17 (G–17) due to the planned decommission of the Atqasuk, AK (ATK), Non-Directional Beacon (NDB) in the vicinity of Atqasuk, AK.

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0539 in the **Federal Register** (87 FR 32371; May 31, 2022), revoking Colored Federal airway G–17 due to the planned decommissioning of the Atqasuk, AK, NDB in the vicinity of Atqasuk, AK. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Green Federal airways are published in paragraph 6009(a) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway G–17 due to the planned decommissioning of the Atqasuk, AK, NDB in the vicinity of Atqasuk, AK. The amendment is described below.

G–17: G–17 extends between the Wainwright Village, AK, NDB and the Atqasuk, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway G–17, due to the planned decommissioning of the Atqasuk, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(a) Green Federal Airways.

* * * * *

G–17 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26164 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0300; Airspace Docket No. 22–AAL–19]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 8 (B–8); Shishmaref, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Blue 8 (B–8) due to the planned decommissioning of the Shishmaref, AK (SHH), Non-Directional Beacon (NDB) in the vicinity of Shishmaref, AK.

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0300 in the **Federal Register** (87 FR 19035; April 1, 2022), revoking Colored Federal airway B–8 due to the planned decommissioning of the Shishmaref, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Blue Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway B–8 due to the decommissioning of the Shishmaref, AK, NDB in the vicinity of Shishmaref, AK. The amendment is described below.

B–8: B–8 extends between the Shishmaref, AK, NDB and the Tin City, AK, NDB. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway B–8, due to the planned decommissioning of the Shishmaref, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change

concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(d) Blue Federal Airways.

* * * * *

B–8 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26168 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0245; Airspace Docket No. 21–AAL–8]

RIN 2120–AA66

Amendment to VOR Federal Airway V–436 and Jet Route J–125, and Establishment of United States Area Navigation Route T–399 in the Vicinity of Clear, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on November 1, 2022, that amends Alaskan VHF Omnidirectional Range (VOR) Federal airway V–436 and Jet Route J–125, and establishes United States Area Navigation (RNAV) route T–399 in the vicinity of Clear, AK. In the final rule, the amendments to V–436 addressed in the preamble were incomplete and did not address all of the airway segment amendments being made. Additionally, the final rule referenced the AILEE, AK, route point as a waypoint (WP), in error, in the V–436 and T–399 amendment discussions in the preamble and in the T–399 route description in the regulatory text. The correct characterization of the AILEE, AK, route point is as a Fix. This action corrects the oversight of not including all of the V–436 amendments addressed in the preamble to match the V–436 description in the regulatory text and changes all references of the AILEE, AK, WP to the AILEE, AK, Fix to match the FAA's National Airspace System Resource (NASR) database information.

DATES: Effective date 0901 UTC, December 29, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (87 FR 65675; November 1, 2022), amending Alaskan VOR Federal airway V–436 and Jet Route J–125, and establishing RNAV route T–399 in the vicinity of Clear, AK. Subsequent to publication, the FAA determined that the amendments to V–436 addressed in the preamble were incomplete and did not address all of the airway segment amendments being made. Additionally, the FAA determined that the AILEE, AK, route point was incorrectly identified as a WP. As such, the preamble discussion of the V–436 amendments appear inconsistent with the amended V–436 description listed in the regulatory text and all references of the AILEE, AK, WP do not match the FAA's NASR database information.

This rule corrects the preamble discussion of the V–436 amendments to include all of the airway segment amendments being made and changes all references of the AILEE, AK, WP to the AILEE, AK, Fix. This action does not alter the alignment of the amended V–436 airway or the established T–399 route listed in the final rule.

Alaskan VOR Federal airways are published in paragraph 6010(b) and United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Alaskan VOR Federal airway and RNAV T-route listed in this document will be published subsequently in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the V–436 amendment discussion contained in the preamble and all references of the AILEE, AK, WP in Docket No. FAA–2021–0245, as published in the **Federal Register** of November 1, 2022 (87 FR 65675), FR Doc. 2022–23369, are corrected as follows:

■ 1. In FR Doc. 2022–23369, appearing on page 65676, in the first and second columns, replace the V–436 amendment discussion to read,

''*V–436:* V–436 extends between the Anchorage, AK (ANC), VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) and the Deadhorse, AK (SCC), VOR/DME. This action removes the airway segment

between the Talkeetna, AK (TKA), VOR/DME and the Nenana, AK (ENN), VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) and replaces the removed airway segment with an airway segment that extends between the Talkeetna, AK (TKA), VOR/DME; the AILEE, AK, Fix; and the Fairbanks, AK (FAI), VORTAC. Additionally, the airway segment north of the Nenana, AK, VORTAC to the Deadhorse, AK, VOR/DME is removed as discussed in the NPRM. As amended, V–436 will extend between the Anchorage, AK, VOR/DME and the Fairbanks, AK, VORTAC.''

■ 2. In FR Doc. 2022–23369, appearing on page 65676, in the second column, replace the T–399 establishment discussion to read,

''*T–399:* T–399 is a new RNAV route that extends between the Talkeetna, AK (TKA), VOR/DME and the Nenana, AK (ENN), VORTAC over the AILEE, AK, Fix; the PAWWW, AK, WP; and the SEAHK, AK, WP.''

■ 3. In FR Doc. 2022–23369, appearing on page 65677, correct the table for T–399 Talkeetna, AK (TKA) to Nenana, AK (ENN) [New] to read:

T–399 Talkeetna, AK (TKA) to Nenana, AK (ENN) [New]

Talkeetna, AK (TKA)	VOR/DME	(Lat. 62°17′54.16″ N, long. 150°06′18.90″ W)
AILEE, AK	FIX	(Lat. 63°36′00.04″ N, long. 149°32′23.46″ W)
PAWWW, AK	WP	(Lat. 63°58′06.62″ N, long. 149°35′19.10″ W)
SEAHK, AK	WP	(Lat. 64°22′38.93″ N, long. 149°32′37.92″ W)
Nenana, AK (ENN)	VORTAC	(Lat. 64°35′24.04″ N, long. 149°04′22.34″ W)

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26171 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0335; Airspace Docket No. 22–AAL–17]

RIN 2120–AA66

Revocation of Colored Federal Airway Amber 2 (A–2); Northway, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Amber 2 (A–2) due to the planned decommissioning of the Nebesna, AK (AES), Non-Directional Beacon (NDB) in the vicinity of Northway, AK.

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2022–0335 in the **Federal Register** (87 FR 19823; April 6, 2022), revoking Colored Federal airway A–2 due to the planned decommissioning of the Nebesna, AK, NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Amber Federal airways are published in paragraph 6009(c) of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway A–2 due to the planned decommissioning of the Nebesna, AK, NDB in the vicinity of Northway, AK. The amendment is described below.

A–2: A–2 extends between the Beaver Creek, YT, Canada, NDB and the Delta Junction, AK, NDB, excluding the airspace within Canada. The airway is removed in its entirety.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine

matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of revoking Colored Federal airway A–2, due to the planned decommissioning of the Nebesna, AK, NDB, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5k, which categorically excludes from further environmental review the publication of existing air traffic control procedures that do not essentially change existing tracks, create new tracks, change altitude, or change concentration of aircraft on these tracks. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6009(c) Amber Federal Airways.

* * * * *

A–2 [Removed]

* * * * *

Issued in Washington, DC, on November 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–26167 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9968]

RIN 1545–BQ16

Affordability of Employer Coverage for Family Members of Employees; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction.

SUMMARY: This document includes corrections to the final regulations (Treasury Decision 9968) published in the **Federal Register** on Thursday, October 13, 2022. This correction contains final regulations under section 36B of the Internal Revenue Code (Code) that amend the regulations regarding eligibility for the premium tax credit (PTC) to provide that affordability of employer-sponsored minimum essential coverage (employer coverage) for family members of an employee is determined based on the employee's share of the cost of covering the employee and those family members, not the cost of covering only the employee.

DATES: These corrections are effective on December 12, 2022.

FOR FURTHER INFORMATION CONTACT: Clara Raymond at (202) 317–4718 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9968) subject to this correction are issued under section 36B of the Internal Revenue Code.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Corrections of Publication

Accordingly, the final regulations (TD 9968) that are the subject of the FR Doc. 2022–22184 starting on page 61979 in the **Federal Register** on Thursday, October 13, 2022, are corrected to read as follows:

§ 1.36B–2 [Corrected]

■ 1. On page 62001, in the first column, in amendatory instruction 3, part ''j'' is corrected to read ''j. Revising the headings for newly redesignated paragraphs (c)(3)(v)(D)(*10*) through (*13*).''.

■ 2. On page 62002, in the second column, in § 1.36B–2, the revised headings for newly redesignated paragraphs (c)(3)(v)(D)(*10*) through (*13*) are added to read as follows:

§ 1.36B–2 [Corrected]

* * * * *

(c) * * *

(3) * * *

(v) * * *

(D) * * *

(*10*) *Example 10: Determination of unaffordability for part of plan year (part-year period).* * * *

(*11*) *Example 11: Affordability determined for part of a taxable year (part-year period).* * * *

(*12*) *Example 12: Coverage unaffordable at year end.* * * *

(*13*) *Example 13: Wellness program incentives.* * * *

* * * * *

Oluwafunmilayo A. Taylor,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2022–25429 Filed 12–1–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0906]

Safety Zone; Sausalito Lighted Boat Parade Fireworks Display, Richardson Bay, Sausalito, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone in the navigable waters of Richardson Bay, off Sausalito, CA, in support of the Sausalito Lighted Boat Parade Fireworks Display. This safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with pyrotechnics. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone, unless authorized by the designated Patrol Commander (PATCOM) or other federal, state, or local agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulation in 33 CFR 165.1191, will be enforced for the location in Table 1 to § 165.1191, Item number 30, from 11 a.m. through 8:35 p.m. on December 10, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email MST1 Shannon Curtaz-Milian, Sector San Francisco Waterways Management, U.S. Coast Guard; telephone 415–399–3585, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 30, for the Sausalito Lighted Boat Parade Fireworks on December 10, 2022. The Coast Guard will enforce a 100-foot safety zone around the fireworks barge during the loading, transit, and setup of the fireworks barge from the loading location to the display location and until the commencement of the fireworks display. From 11 a.m. until 2 p.m. on December 10, 2022, the fireworks barge will be loading pyrotechnics at Pier 50 in San Francisco, CA. The fireworks barge will remain at the loading location until its transit to the display location. From 6:30 p.m. to 7:30 p.m. on December 10, 2022 the loaded fireworks barge will transit from Pier 50 to the launch site near Sausalito Point in approximate position 37°51′11.88″ N, 122°28′25.67″ W (NAD 83), where it will remain until the conclusion of the fireworks display. Starting at 7:30 p.m. on December 10, 2022, 30 minutes prior to the commencement of the 5-minute fireworks display, the safety zone will encompass the navigable waters, from surface to bottom, surrounding the fireworks barge near Spinnaker Point in Sausalito, CA within a radius of 1,000 feet from approximate position 37°51′11.88″ N, 122°28′25.67″ W (NAD 83) for the Sausalito Lighted Boat Parade Fireworks Display as set forth in 33 CFR 165.1191, Table 1, Item number 30. The safety zone will be enforced through 8:35 p.m. on December 10, 2022.

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

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM or other Official Patrol defined as a federal, state, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. Additionally, each person who receives notice of a lawful order or direction issued by the PATCOM or Official Patrol shall obey the order or direction. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Marine Information Broadcast, the Local Notice to Mariners, and/or actual notice may be used to grant general permission to enter the regulated area.

Dated: November 23, 2022.

Taylor Q. Lam,

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

[FR Doc. 2022–26257 Filed 12–1–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0931]

RIN 1625–AA00

Safety Zone; Gulf Intracoastal Waterway, Lake Charles, LA

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Gulf Intracoastal Waterway between the Calcasieu Lock at Mile Marker 238.2 and Mile Marker 240 at the Lake Charles Industrial Canal. The safety zone is needed to protect personnel, vessels, and the marine environment from hazards created by a large spill of heavy crude oil. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Port Arthur.

DATES: This rule is effective without actual notice from December 2, 2022, through December 4, 2022. For the purposes of enforcement, actual notice will be used from November 28, 2022, until December 2, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0931 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 on this rule, call or email Mr. Scott Whalen, Marine Safety Unit Port Arthur, TX, U.S. Coast Guard; telephone 409–719–5086, email *scott.k.whalen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
COTP Captain of the Port, Marine Safety Unit Port Arthur
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 without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This 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.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because an approximately 95 barrel spill of heavy oil occurred on the Gulf Intracoastal Waterway west of the Calcasieu Lock in Lake Charles, LA, and immediate action is needed to respond to the spill and protect persons, vessels, and the environment from hazards associated with the spill and response effors. It is impracticable to publish an NPRM

because we must establish this safety zone by immediately.

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 impracticable because immediate action is needed to respond to the spill and protect persons, vessels, and the environment from hazards associated with the spill and response effors.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Port Arthur (COTP) has determined that potential hazards associated with a 95 barrel spill of heavy oil into the Gulf Intracoastal Waterway is a safety concern for the environment and persons or vessels transiting through the area. This rule is needed to protect personnel, vessels, and the marine environment from the hazards of the spill and associated response efforts.

IV. Discussion of the Rule

This rule establishes a safety zone from 6 p.m. on November 28, 2022, through 6 p.m. on December 4, 2022. The safety zone will cover all navigable waters, shoreline to shoreline, of the Gulf Intracoastal Waterway between the Calcasieu Lock at Mile Marker 238.2 west to Mile Marker 240 near the Lake Charles Industrial Canal. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while spill response operations are ongoing. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the limited size and duration of the rule.

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 only 6-days that will prohibit entry into the Gulf Intracoastal Waterway, shoreline to shoreline, between the Calcasieu Lock at Mile Marker 238.2 west to Mile Marker 240. 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. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0931 to read as follows:

§ 165.T08–0931 Safety Zone; Gulf Intracoastal Waterway, Lake Charles, LA.

(a) *Location.* The following area is a safety zone: All waters of the Gulf Intracoastal Waterway, shoreline to shoreline, from the Calcasieu Lock at Mile Marker 238.2 west to Mile Marker 240 at the Lake Charles Industrial Canal.

(b) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Port Arthur (COTP) or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by calling the Command Duty Officer at (337) 912–0073. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

Dated: November 28, 2022.

James B. Suffern,

Captain, U.S. Coast Guard, Acting Captain of the Port, Marine Safety Unit Port Arthur.

[FR Doc. 2022–26298 Filed 12–1–22; 8:45 am]

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Copyright Royalty Board

37 CFR Part 380

[Docket No. 19–CRB–0005–WR (2021–2025) COLA (2023)

Cost of Living Adjustment to Royalty Rates for Webcaster Statutory License

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) in the royalty rates that commercial and noncommercial noninteractive webcasters pay for eligible transmissions pursuant to the statutory licenses for the public performance of and for the making of ephemeral reproductions of sound recordings.

DATES:

Effective date: December 2, 2022.

Applicability date: These rates are applicable to the period January 1, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Anita Brown, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Sections 112(e) and 114(f) of the Copyright Act, title 17 of the United States Code, create statutory licenses for certain digital performances of sound recordings and the making of ephemeral reproductions to facilitate transmission of those sound recordings. On October 27, 2021, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under those licenses for the license period 2021–2025 for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. *See* 86 FR 59452.

Pursuant to those regulations, at least 25 days before January 1 of each year from 2022 to 2025, the Judges shall publish in the **Federal Register** notice of a COLA applicable to the royalty fees for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. 37 CFR 380.10.

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the CPI–U from the CPI–U published in November 2020 (260.229), according to the formula: for subscription performances, $(1 + (C_y - 260.229)/260.229) \times \$0.0026$; for nonsubscription performances, $(1 + (C_y - 260.229)/260.229) \times \$0.0021$; for performances by a noncommercial webcaster in excess of 159,140 ATH per month, $(1 + (C_y - 260.229)/260.229) \times \$0.0021$; where C_y is the CPI–U published by the Secretary of Labor before December 1 of the preceding year. The adjusted rate shall be rounded to the nearest fourth decimal place. 37 CFR 380.10(c). The CPI–U published by the Secretary of Labor from the most recent index published before December 1, 2022, is 298.012.[1] Applying the formula in 37 CFR 380.10(c) and rounding to the nearest fourth decimal place results in an increase in the rates for 2023.

The 2023 rate for eligible transmissions of sound recordings by commercial webcasters is $0.0030 per subscription performance and $0.0024 per nonsubscription performance.

Application of the increase to rates for noncommercial webcasters results in a 2023 rate of $0.0024 per performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

As provided in 37 CFR 380.10(d), the royalty fee for making ephemeral recordings under section 112 of the Copyright Act to facilitate digital transmission of sound recordings under section 114 of the Copyright Act is included in the section 114 royalty fee and comprises 5% of the total fee.

List of Subjects in 37 CFR Part 380

Copyright; sound recordings.

Final Regulations

In consideration of the foregoing, the Judges amend part 380 of title 37 of the Code of Federal Regulations as follows:

PART 380—RATES AND TERMS FOR TRANSMISSIONS BY ELIGIBLE NONSUBSCRIPTION SERVICES AND NEW SUBSCRIPTION SERVICES AND FOR THE MAKING OF EPHEMERAL REPRODUCTIONS TO FACILITATE THOSE TRANSMISSIONS

■ 1. The authority citation for part 380 continues to read as follows:

Authority: 17 U.S.C. 112(e), 114(f), 804(b)(3).

■ 2. Section 380.10 is amended by revising paragraph (a) to read as follows:

[1] This CPI–U was announced on November 10, 2022, by the Bureau of Labor Statistics in its *Consumer Price Index News Release—Consumer Price Index,* available at *https://www.bls.gov/news.release/cpi.htm* at Table 1.

§ 380.10 Royalty fees for the public performance of sound recordings and the making of ephemeral recordings.

(a) *Royalty fees.* For the year 2023, Licensees must pay royalty fees for all Eligible Transmissions of sound recordings at the following rates:

(1) *Commercial webcasters:* $0.0030 per Performance for subscription services and $0.0024 per Performance for nonsubscription services.

(2) *Noncommercial webcasters:* $1,000 per year for each channel or station and $0.0024 per Performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

* * * * *

Dated: November 28, 2022.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2022–26229 Filed 12–1–22; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 386

[Docket No 22–CRB–0008–SA–COLA (2023)]

Cost of Living Adjustment to Satellite Carrier Compulsory License Royalty Rates

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Final rule; cost of living adjustment.

SUMMARY: The Copyright Royalty Judges announce a cost of living adjustment (COLA) of 7.7% in the royalty rates satellite carriers pay for a compulsory license under the Copyright Act. The COLA is based on the change in the Consumer Price Index from October 2021 to October 2022.

DATES:

Effective date: December 2, 2022.

Applicability date: These rates are applicable to the period January 1, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Anita Brown, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: The satellite carrier compulsory license establishes a statutory copyright licensing scheme for the distant retransmission of television programming by satellite carriers. 17 U.S.C. 119. Congress created the license in 1988 and reauthorized the license for additional five-year periods until 2019 when it made the license permanent.[1]

On August 31, 2010, the Copyright Royalty Judges (Judges) adopted rates for the section 119 compulsory license for the 2010–2014 term. *See* 75 FR 53198. The rates were proposed by Copyright Owners and Satellite Carriers[2] and were unopposed. *Id.* section 119(c)(2) of the Copyright Act provides that, effective January 1 of each year, the Judges shall adjust the royalty fee payable under section 119(b)(1)(B) ''to reflect any changes occurring in the cost of living as determined by the most recent Consumer Price Index (for all consumers and for all items) [CPI–U] published by the Secretary of Labor before December 1 of the preceding year.'' Section 119 also requires that ''[n]otification of the adjusted fees shall be published in the **Federal Register** at least 25 days before January 1.'' 17 U.S.C. 119(c)(2).

The change in the cost of living as determined by the CPI–U during the period from the most recent index published before December 1, 2021, to the most recent index published before December 1, 2022, is 7.7%.[3] Application of the 7.7% COLA to the current rate for the secondary transmission of broadcast stations by satellite carriers for private home viewing—32 cents per subscriber per month— results in a rate of 34 cents per subscriber per month (rounded to the nearest cent). *See* 37 CFR 386.2(b)(1). Application of the 7.7% COLA to the current rate for viewing in commercial establishments—65 cents per subscriber per month—results in a rate of 70 cents per subscriber per month (rounded to the nearest cent). *See* 37 CFR 386.2(b)(2).

List of Subjects in 37 CFR Part 386

Copyright, Satellite, Television.

Final Regulations

In consideration of the foregoing, the Judges amend part 386 of title 37 of the Code of Federal Regulations as follows:

[1] The most recent five-year reauthorization was pursuant to the STELA Reauthorization Act of 2014, Public Law 113–200. The license was made permanent by the Satellite Television Community Protection and Promotion Act of 2019, Public Law 116–94, div. P, title XI, § 1102(a), (c)(1), 133 Stat. 3201, 3203.

[2] Program Suppliers and Joint Sports Claimants comprised the Copyright Owners while DIRECTV, Inc., DISH Network, LLC, and National Programming Service, LLC, comprised the Satellite Carriers.

[3] On November 10, 2022, the Bureau of Labor Statistics announced that the CPI–U increased 7.7% over the last 12 months.

PART 386—ADJUSTMENT OF ROYALTY FEES FOR SECONDARY TRANSMISSIONS BY SATELLITE CARRIERS

■ 1. The authority citation for part 386 continues to read as follows:

Authority: 17 U.S.C. 119(c), 801(b)(1).

■ 2. Section 386.2 is amended by adding paragraphs (b)(1)(xiv) and (b)(2)(xiv) to read as follows:

§ 386.2 Royalty fee for secondary transmission by satellite carriers.

* * * * *

(b) * * *

(1) * * *

(xiv) 2023: 34 cents per subscriber per month.

(2) * * *

(xiv) 2023: 70 cents per subscriber per month.

Dated: November 28, 2022.

David P. Shaw,

Chief Copyright Royalty Judge.

[FR Doc. 2022–26226 Filed 12–1–22; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 721, and 725

[EPA–HQ–OPPT–2020–0588; FRL–8582–01–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (21–1.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and a Microbial Commercial Activity Notice (MCAN). The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the

notice, and has taken such actions as are required by that determination.

DATES: This rule is effective on January 31, 2023. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on December 16, 2022.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: *wysong.william@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. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. 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:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20 or 40 CFR 725.920 for the microorganism), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. How can I access the dockets?

The dockets include information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0588, is available online at *https://www.regulations.gov* and in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Background

A. What action is the Agency taking?

EPA is finalizing SNURs under TSCA section 5(a)(2) for certain chemical substances which were the subject of PMNs and an MCAN. Previously, in the **Federal Register** of June 11, 2021 (86 FR 31239) (FRL–10022–56), EPA proposed SNURs for these chemical substances and established the record for these SNURs in the docket under docket ID number EPA–HQ–OPPT–2020–0588. That docket includes information considered by the Agency in developing the proposed and final rules, including public comments and EPA's responses to the public comments received.

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). in particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

A. Considerations for Significant New Use Determinations

When the Agency issues an order under TSCA section 5(e), section 5(f)(4) requires that the Agency consider whether to promulgate a SNUR for any use not conforming to the restrictions of the TSCA Order or publish a statement describing the reasons for not initiating the rulemaking. TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four

bulleted TSCA section 5(a)(2) factors listed in this unit.

B. Procedures for Significant New Uses Claimed as CBI

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. When this rule was proposed on June 11, 2021 (86 FR 31239) (FRL–10022–56), EPA cross referenced 40 CFR 721.1725(b)(1), the procedures to deal with the situation where a specific significant new use is CBI, in order to apply it other SNURs where certain significant new uses have been claimed as CBI. Since the proposed rule, however, EPA has finalized amendments to 40 CFR 721.11 (87 FR 39756, July 5, 2022), which now provides a means by which bona fide submitters can determine whether their substance is subject to the SNUR and for EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a bona fide intent to manufacture or process a particular chemical substance. As such, EPA has removed the proposed references to 40 CFR 721.1725(b)(1) for SNURs that certain significant new uses have been claimed as CBI because the procedure in 40 CFR 721.11 now applies to all SNURs containing any CBI, including the significant new use.

Under these procedures a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.11 into a single step to identify if a chemical substance is subject to part 721 and if a specific use would be a significant new use under the rule.

IV. Public Comments on Proposed Rule and EPA Responses

EPA received public comments from three identifying entities on the proposed rules. The Agency's responses are presented in the Response to Public Comments document that is available in the public docket for this rulemaking. EPA made a change to one of the proposed rules as described in the response to comments.

EPA made additional changes to the proposed rules because it inadvertently proposed incorrect terms in several SNURs. The revised language better reflects the language used in the underlying TSCA Orders for these chemical substances and these changes make the SNUR requirements consistent with those TSCA Orders. EPA received no comments on these requirements. For the SNURs for P–18–327 at 721.11588, P–18–218 at 721.11581, P–18–217 at 721.11580, and P–18–178 at 721.11579, EPA changed the language in paragraph (a)(1) exempting SNUR requirements from ''completely reacted (cured)'' to ''completely entrained,'' which more accurately reflects the exemption language in the underlying TSCA Orders. For the SNURs for P–16–424 at 721.11574 and P–20–42 at 721.11601, EPA removed the proposed reporting requirement specified at 721.72(g)(2)(iv). This would have required the inclusion of the term ''use respiratory protection'' in hazard communication materials; however, this requirement was not in the underlying TSCA Orders for these two chemical substances. For the SNUR for P–20–42 at 721.11601, EPA added the reporting requirement specified at 721.72(f). This allows persons subject to the SNUR to use any existing hazard communication program that meets the requirements of the SNUR. The underlying TSCA Order for this chemical substance contains this requirement.

V. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for chemical substances in 40 CFR part 721, subpart E. In Unit IV. of the proposed SNURs, EPA provided the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as confidential business information (CBI)).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Effective date of and basis for the TSCA Order.
- Potentially Useful Information. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.
- CFR citation assigned in the regulatory text section of these rules.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the rules, may be claimed as CBI.

These final rules include PMN substances that are subject to orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). Those TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The final SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA Order usually requires that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL). The comprehensive NCELs provisions in TSCA Orders include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. No comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects that persons whose 40 CFR 721.30 requests to use the NCELs approach for SNURs that are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA Order.

VI. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs and as further discussed in Unit IV of the proposed rules, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. Based on such findings, TSCA Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors—not just the original submitter—are held to the same standard.

B. Objectives

EPA is issuing these SNURs because the Agency wants to

- Receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- Have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use; and
- Be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *https://www.epa.gov/tsca-inventory.*

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA Orders have been issued for all the chemical substances that are the subject of this rule, and the PMN submitters are prohibited by the TSCA Orders from undertaking activities which will be designated as significant new uses. The identities of many of the chemical substances subject to this rule have been claimed as confidential (per 40 CFR 720.85). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Furthermore, EPA designated the publication dates of the proposed rules (see Unit II.) as the cutoff dates for determining whether the new uses are ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use identified as of the abovementioned dates, that person will have to cease any such activity upon the effective date of the final rule. To resume their activities, that person would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, TSCA Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, TSCA Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to them or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs listed in this document. Descriptions are provided for informational purposes. The information identified in Unit IV. of the proposed rule will be potentially useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce.*

The potentially useful information identified in Unit IV. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance associated with the designated significant new uses. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analyses are available in each docket listed in Unit II.

XI. Statutory and Executive Order Reviews

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

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

This action establishes SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The information collection requirements associated with SNURs have already been approved by OMB pursuant to the PRA under OMB control number 2070–0012 (EPA ICR No. 574). This rule does not impose any burden requiring additional OMB approval.

The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. The Information Collection Request (ICR) covering the SNUR activities was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

C. Regulatory Flexibility Act (RFA)

Pursuant to the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, EPA has concluded that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 10 in Federal fiscal year (FY) FY2016, 14 in FY2017, 16 in FY2018, five in FY2019, seven in FY2020, and 13 in FY2021, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $19,020 to $3,330. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $11,164 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action will not have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal

governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

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 this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

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 containing this rule and other required information 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).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 725

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

Dated: November 17, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

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

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, amend the table by adding in numerical order entries for §§ 721.11571 through 721.11602 under the undesignated center heading ''Significant New Uses of Chemical Substances'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Significant New Uses of Chemical Substances	
* * * * *	
721.11571	2070–0012
721.11572	2070–0012
721.11573	2070–0012
721.11574	2070–0012
721.11575	2070–0012
721.11576	2070–0012
721.11577	2070–0012
721.11578	2070–0012
721.11579	2070–0012
721.11580	2070–0012
721.11581	2070–0012
721.11582	2070–0012
721.11583	2070–0012
721.11584	2070–0012
721.11585	2070–0012
721.11586	2070–0012
721.11587	2070–0012
721.11588	2070–0012
721.11589	2070–0012
721.11590	2070–0012
721.11591	2070–0012
721.11592	2070–0012
721.11593	2070–0012
721.11594	2070–0012
721.11595	2070–0012
721.11596	2070–0012
721.11597	2070–0012
721.11598	2070–0012
721.11599	2070–0012
721.11600	2070–0012
721.11601	2070–0012
721.11602	2070–0012
* * * * *	

* * * * *

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

Subpart E—Significant New Uses for Specific Chemical Substances

■ 4. Add §§ 721.11571 through 721.11602 in numerical order to subpart E to read as follows:

Sec.

* * * * *

721.11571 Hindered amine alkyl ester compounds (generic).
721.11572 N-alkyl-dialkylpiperidine (generic).
721.11573 Tetraalkylpiperidinium halide (generic).
721.11574 Tetraalkylpiperidinium hydroxide (generic).
721.11575 Amidoamino quaternary ammonium salt (generic).
721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).
721.11577 Benzenediamine, ar-chloro-ar, ar-diethyl-ar-methyl-.
721.11578 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.
721.11579 Dialkyltin dialkylcarboxylate (generic).

721.11580 Alkyltin dodecylthioester (generic).
721.11581 Alkyltin tetradecylthioester (generic).
721.11582 Undecanol, branched.
721.11583 Hydroxy alkanoic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).
721.11584 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2'-[1,6-hexanediylbis(oxymethylene)] bis[oxirane], 4,4'-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxymethyl]oxirane (generic).
721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester.
721.11586 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1).
721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.
721.11588 Mixed metal oxide (generic).
721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).
721.11590 Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.
721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.
721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.
721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.
721.11594 Alkenylamide (generic).
721.11595 Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).
721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2'-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4'-(1-alkylidene)bis[phenol], 2,2'-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).
721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2'[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).
721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).
721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).
721.11600 Octanal, 7(or 8)-formyl-.
721.11601 Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).
721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

* * * * *

§ 721.11571 Hindered amine alkyl ester compounds (generic).

(a) *Chemical substance and significant new uses subject to reporting.* The chemical substance generically identified as hindered amine alkyl ester compounds (PMN P–16–167) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iv), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure of confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets), gas/vapor (all substances in gas form), and combination gas/vapor and particulate (gas and liquid/solid physical states are present).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; respiratory complications; central nervous system effects; blood effects. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11572 N-alkyl-dialkylpiperidine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as N-alkyl-dialkylpiperidine (PMN P–16–419) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include gas/vapor (all substances in the gas form). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(h).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=286.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11573 Tetraalkylpiperidinium halide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraalkylpiperidinium halide (PMN P–16–423) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), the substance may cause: acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 20.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11574 Tetraalkylpiperidinium hydroxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tetraalkylpiperidinium hydroxide (PMN P–16–424) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3), (b), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(ii), (g)(4), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; acute toxicity; specific target organ toxicity; reproductive toxicity. For purposes of § 721.72(g)(4), notice to users: water release restrictions apply. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=20.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11575 Amidoamino quaternary ammonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as amidoamino quaternary ammonium salt (PMN P–17–235) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 44.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11576 Tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as tri alkyl, mono alkoxy, fatty acid ester, ammonium salt (PMN P–18–226) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 44.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11577 Benzenediamine, ar-chloro-ar, ar-diethyl-ar-methyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenediamine, ar-chloro-ar, ar-

diethyl-ar-methyl- (PMN P–17–259; CAS No. 1616795–05–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11578 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear (PMN P–18–43; CAS No. 2097734–13–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=2.

(ii) [Reserved]

(b) *Specific requirements.* The provision of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11579 Dialkyltin dialkylcarboxylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dialkyltin dialkylcarboxylate (PMN P–18–178) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11580 Alkyltin dodecylthioester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin dodecylthioester (PMN P–18–217) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section

§ 721.11581 Alkyltin tetradecylthioester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkyltin tetradecylthioester (PMN P–18–218) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), and (c). When determining which persons are likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a stabilizer for PVC compounds.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), (i), and (k) are

applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section

§ 721.11582 Undecanol, branched.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as undecanol, branched (PMN P–18–256; CAS No. 203743–00–4) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 4.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11583 Hydroxy alkanoic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as hydroxy alkanoic acid, compds. with aminoalkoxyalcohol-epoxy polymer-alkanolamine reaction products (PMN P–18–283) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(ii), (g)(4)(iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin sensitization; eye irritation; specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11584 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2′-[1,6-hexanediylbis(oxymethylene)]bis[oxirane], 4,4′-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy methyl]oxirane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with ethyleneamine, 2-(chloromethyl)oxirane, 2-[[4-(1,1-dimethylethyl)phenoxy]methyl]oxirane, 2,2′-[1,6-hexanediylbis(oxymethylene)] bis[oxirane], 4,4′-(1-methylethylidene)bis[phenol], alkyl ether amine, and 2-[(2-methylphenoxy methyl]oxirane (PMN P–18–298) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance for an application method that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N=50.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11585 Benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as benzenepropanoic acid, 3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxy-, 2,2-bis(hydroxymethyl)butyl ester (PMN P–18–310; CAS No. 2101609–93–0) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include gas/vapor and particulate.

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.16 mg/m^3 as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator

requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11586 1-Octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-octadecanaminium, N,N-dimethyl-N-[3-(triethoxysilyl)propyl]-, chloride (1:1) (PMN P–18–318; CAS No. 62117–57–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a surface treatment for added lubricity and anti-static properties. It is a significant new use to use the substance in an application method that results in inhalation exposure to workers.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11587 2-Propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, 3-methyl-3-buten-1-yl ester (PMN P–18–323; CAS No. 156291–88–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets) and gas/vapor (all substances in the gas form).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), (g)(4)(i) through (iii), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; developmental effects; systemic effects; respiratory effects; skin sensitization; respiratory sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* Requirements as specified in § 721.80(k).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 98.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11588 Mixed metal oxide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as mixed metal oxide (PMN P–18–327) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely entrained.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.1 mg/m^3 as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so

under § 721.30. Persons whose § 721.30 requests to use NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) consent order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (g)(2), and (g)(5). For purposes of § 721.72(g)(1), this substance may cause: cancer; skin sensitization; respiratory sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used. For purposes of § 721.72(g)(2), when using this substance: avoid skin contact, avoid breathing substance, avoid ingestion, use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 0.1 mg/m^3, and use skin protection.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11589 Amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as amines, polyethylenepoly-, triethylenetetramine fraction, polymers with guanidine hydrochloride (1:1) (PMN P–18–347; CAS No. 1902936–67–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) and (v), (g)(3)(i) and (ii), (g)(4)(i), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 2.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11590 Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phenol, 4,4′-(1-methylethylidene)bis-, polymer with 3,6,9,12-tetraoxatetradeca-1, 13-diene, glycidyl ether (PMN P–18–405; CAS No. 647028–24–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11591 1,4-Benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,4-benzenedicarboxylic acid, 1,4-bis(2-phenoxyethyl) ester (PMN P–19–36; CAS No. 25900–07–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3) through (6), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure of confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 3.

(b) *Specific requirements.* The provisions of subpart A of this part may apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11592 Poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl), .alpha.-nonyl-.omega.-hydroxy-, branched and linear

(PMN P–19–52; CAS No. 2242406–13–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) through (iii), (a)(3) through (6), (b), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (a)(4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000. For purposes of § 721.63(a)(6), the airborne form(s) of the substance include particulate (including solids or liquid droplets). For purposes of § 721.63(b), the concentration is set at 1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; respiratory complications; internal organ effects; eye corrosion. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* It is a significant new use to use the substance where the concentration of the substance in the product formulation intended for distribution in commerce exceeds 1% by weight.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 34.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11593 1-Butanamine, N-butyl-N-[(triethoxysilyl)methyl]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-butanamine, N-butyl-N-[(triethoxysilyl)methyl]- (PMN P–19–53; CAS No. 35501–23–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1) and (3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (o). It is a significant new use to process and use the substance other than in a liquid formulation.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (e), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11594 Alkenylamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenylamide (PMN P–19–77) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k).

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 4.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11595 Isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as isoalkylaminium, N-isoalkyl, -N, N-dimethyl chloride (PMN P–19–131) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or destroyed (*e.g.,* reacted to bind with clay).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11596 Aldehyde, polymer with mixed alkane polyamines, 2,2′-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4′-(1-alkylidene)bis[phenol], 2,2′-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aldehyde, polymer with mixed alkane polyamines, 2,2′-[1,4-alkanediylbis(oxyalkylene)]bis[oxirane], 2-(alkoxyalkyloxirane, 4,4′-(1-alkylidene)bis[phenol], 2,2′-[(1-alkylidene)bis(4,1-alkyleneoxyalkylene)]bis[oxirane] and 2-(aryloxyalkyl)oxirane, acetate (salt) (PMN P–19–143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11597 Alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2′[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkanedioic acid, compds. with substituted arylalkylamine-arylalcohol disubstituted alkane-the diglycidyl ether of a arylalcohol disubstituted alkane-epichlorohydrin-aldehyde-2,2′[(1-alkylidene)bis[4,1-aryleneoxy(alkyl-2,1-alkanediyl)oxyalkylene]]bis[oxirane]-alkanepolyamine polymer-1-[[2-[(2-aminoalkyl)amino]alkyl]amino]-3-aryloxy-2-alcohol reaction products (PMN P–19–144) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured) or destroyed.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure to either the PMN substance or to formaldehyde.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11598 Polyazaalkane with oxirane and methyloxirane, haloalkane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as polyazaalkane with oxirane and methyloxirane, haloalkane (PMN P–19–145) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1%. For purposes of § 721.72(g)(1), this substance may cause: reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the PMN substance in a manner that results in inhalation exposure.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 26.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f) through (h), (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11599 Dibromoalkyl ether tetrabromobisphenol A (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as dibromoalkyl ether tetrabromobisphenol A (PMN P–19–153) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(3)(ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: eye irritation; carcinogenicity; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are

applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11600 Octanal, 7(or 8)-formyl-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as octanal, 7(or 8)-formyl- (PMN P–20–29; CAS No. 1607842–40–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 17.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11601 Sulfonium, trisaryl-, 7, 7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as sulfonium, trisaryl-, 7, 7-dialkyl-2-heteropolycyclic-1-alkanesulfonate (1:1) (PMN P–20–42) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or adhered (during the photolithographic process) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i) and (iii), (a)(3), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii) and (v), (g)(3)(i) and (ii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; acute toxicity; skin sensitization; serious eye damage; specific target organ toxicity; neurotoxicity; genetic toxicity; reproductive toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (t). It is a significant new use to import the PMN substance other than in solution, unless in sealed containers weighing 5 kilograms or less. It is a significant new use to process the PMN substance in any way that generates a dust, mist, or aerosol in a non-enclosed process. It is a significant new use to manufacture the PMN substance longer than 18 months.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11602 Alkenoic acid, polymer with (alkyl alkenyl) polyether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as alkenoic acid, polymer with (alkyl alkenyl) polyether (PMN P–20–104) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to manufacture, process, or use the substance in a manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4) and (c)(4), where N = 75.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain modification requirements.* The provisions of § 721.185 apply to this section.

* * * * *

PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

■ 3. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

■ 4. Add § 725.1081 to read as follows:

§ 725.1081 Trichoderma reesei modified (generic).

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically modified microorganism generically identified as *Trichoderma reesei* modified (MCAN J–16–26) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) It is a significant new use to manufacture, process, or use the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (*i.e.,* for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium); and

(B) Any fermentation of solid plant material or insoluble substrate to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in § 725.422(d).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart L of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 725.950(b)(2) through (4) are applicable to manufacturers and processors of this microorganism.

(2) *Modification or revocation of certain notification requirements.* The provisions of § 725.984 apply to this section.

[FR Doc. 2022–25807 Filed 12–1–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2021–0845; FRL–9075–02–OAR]

RIN 2060–AV55

Renewable Fuel Standard Program: Canola Oil Pathways to Renewable Diesel, Jet Fuel, Naphtha, Liquefied Petroleum Gas, and Heating Oil

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, EPA determines that renewable diesel, jet fuel, heating oil, naphtha, and liquefied petroleum gas (LPG) produced from canola/rapeseed oil via a hydrotreating process all meet the lifecycle greenhouse gas (GHG) emissions reduction threshold of 50 percent required for advanced biofuels and biomass-based diesel (BBD) under the Renewable Fuel Standard (RFS) program. Based on the analyses described in the earlier notice of proposed rulemaking associated with this action, EPA is adding these pathways to the list of approved pathways in the RFS regulations, making them eligible to generate Renewable Identification Numbers (RINs), provided they satisfy the other definitional and RIN generation criteria for renewable fuel specified in the RFS regulations. EPA is also amending the RFS regulations by adding a new definition of ''canola/rapeseed oil.''

DATES: This rule is effective on January 3, 2023.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2021–0845. All documents are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Christopher Ramig, Office of Air and Radiation, Office of Transportation and Air Quality, Mail Code: 6401A, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–564–1372; email address: *ramig.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

Entities potentially affected by this final rule are those involved with the production, distribution, and sale of transportation fuels, including gasoline and diesel fuel or renewable fuels such as biodiesel, heating oil, renewable diesel, naphtha, and LPG. Potentially regulated categories include:

Category	NAICS [1] code	Examples of potentially affected entities
Industry	111120	Oilseed (except Soybean) Farming.
Industry	324110	Petroleum refineries (including importers).
Industry	325199	Other basic organic chemical manufacturing.
Industry	424690	Chemical and allied products merchant wholesalers.
Industry	424710	Petroleum Bulk Stations and Terminals.
Industry	424720	Petroleum and Petroleum Products Merchant Wholesalers.
Industry	454310	Other fuel dealers.

[1] North American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated or otherwise affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria in the referenced regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Table of Contents

I. Introduction

Section 211(o) of the Clean Air Act (CAA) establishes the RFS program, under which EPA sets annual percentage standards specifying the total amount of renewable fuel, as well as three subcategories of renewable fuel, that must be used to reduce or replace fossil fuel present in transportation fuel, heating oil, or jet fuel. Non-exempt renewable fuels must achieve at least a 20 percent reduction in lifecycle GHG emissions as compared to a 2005 petroleum baseline. Advanced biofuel and BBD must achieve at least a 50 percent reduction, and cellulosic biofuel must achieve at least a 60 percent reduction.[1]

In addition to having to meet the applicable lifecycle GHG reduction requirements, a fuel may only generate RINs if it meets the definitional and other criteria for renewable fuel (*e.g.,* feedstock is a qualifying source of

[1] See, generally, 42 U.S.C. 7545(o)(1).

renewable biomass as defined in the regulations and used to reduce or replace the quantity of fossil fuel present in transportation fuel, heating oil, or jet fuel) in CAA section 211(o) and the RFS regulations at 40 CFR part 80, subpart M.

Only fuels produced using pathways that EPA has approved as meeting all applicable requirements are eligible to generate RINs. There are three critical components of fuel pathways under the RFS program: (1) fuel type; (2) feedstock; and (3) production process. Each approved pathway is associated with a specific ''D code'' corresponding to whether the fuel meets the requirements for renewable fuel, advanced fuel, cellulosic fuel, or BBD.[2] Since the formation of the RFS program, EPA has periodically promulgated rules to add new pathways to the regulations.[3] In addition, EPA has approved facility-specific pathways through the petition process in 40 CFR 80.1416.

EPA's lifecycle analyses are used to assess the overall GHG impacts of a fuel throughout each stage of its production and use. The results of these analyses, considering uncertainty and the weight of available evidence, are used to determine whether a fuel meets the necessary GHG reduction threshold required under the CAA. Lifecycle analysis includes an assessment of emissions related to the full fuel lifecycle, including feedstock production, feedstock transportation, fuel production, fuel transportation and distribution, and tailpipe emissions. Per the CAA definition of lifecycle GHG emissions,[4] EPA's lifecycle analyses also include an assessment of significant indirect emissions, such as those from land use changes (LUC) and agricultural sector impacts.

EPA conducted lifecycle GHG analyses for several combinations of biofuel feedstocks, production processes, and fuels and promulgated several fuel pathways as part of its March 26, 2010 RFS2 final rule (75 FR 14670) (the ''March 2010 RFS2 rule''). In the preamble to that final rule, EPA indicated that it intended to add fuel pathways to the regulations via further notice-and-comment rulemakings. EPA subsequently completed a proposed assessment for canola oil biodiesel; this proposed assessment was published in the **Federal Register** for notice and comment on July 26, 2010 (75 FR 43522). This proposed assessment evaluated the GHG emissions associated with biodiesel produced from canola oil through a transesterification process. On September 28, 2010, EPA published a rule finalizing our determination that canola oil biodiesel meets the lifecycle GHG emissions reduction threshold of 50 percent required by the CAA and added row G to Table 1 to 40 CFR 80.1426, making canola oil biodiesel produced through a transesterification process eligible for BBD (D–code 4) RINs (75 FR 59622) (the ''September 2010 Canola Oil rule''). This final rule did not include determinations for renewable diesel, jet fuel, naphtha, LPG, or heating oil produced from canola oil via a hydrotreating process.[5] In the 2013 Pathways I final rule (78 FR 14190, March 5, 2013) (the ''2013 Pathways I rule''), EPA added rapeseed oil as a feedstock in the existing pathway in row G for renewable fuel made from canola oil because ''we had not intended the supplemental determination to cover just those varieties or sources of rapeseed that are identified as canola'' (78 FR 14214). In that same rule, for clarity EPA also added ''heating oil'' to the rows in Table 1 to 40 CFR 80.1426 that already included renewable diesel or biodiesel (78 FR 14201). As in the 2013 Pathways I rule, in this action we are similarly adding new pathways to Table 1 to 40 CFR 80.1426 for biofuels produced from ''canola/rapeseed oil'' but for simplicity we refer to both canola and rapeseed as ''canola'' throughout this preamble.

In 2020, the United States Canola Association (USCA) submitted a rulemaking petition to EPA requesting an evaluation of the GHG emissions associated with renewable diesel, jet fuel, naphtha, LPG, and heating oil produced from canola oil via a hydrotreating process, and a determination of the renewable fuel categories, if any, for which such biofuels may be eligible.[6]

In response to the USCA petition, EPA conducted an analysis of the lifecycle GHG emissions associated with these fuel pathways. In April 2022, we published this analysis as part of the notice of proposed rulemaking (87 FR 22823, April 18, 2022) (the ''Canola NPRM'') associated with this final rulemaking.[7]

As described in the Canola NPRM preamble, we estimated the lifecycle GHG emissions associated with the production of renewable diesel, naphtha, LPG, and jet fuel via a hydrotreating process. The Canola NPRM preamble discussed these estimates and our consideration of uncertainty in the analysis. Based on this analysis, we proposed to find that these biofuels meet the 50 percent GHG reduction threshold required for advanced biofuel and BBD. In the Canola NPRM, we also proposed a definition of ''canola/rapeseed oil'' to provide clarity about which feedstocks would qualify under these proposed pathways.

In this final action, EPA is adding to Table 1 of 40 CFR 80.1426 pathways for the production of renewable diesel, jet fuel, naphtha, LPG, and heating oil produced from canola oil via a hydrotreating process, as proposed. Upon the effective date of this action, these fuel pathways are eligible for either BBD (D–code 4) or advanced biofuel (D–code 5) RINs, depending on the fuel type and whether they are produced through a hydrotreating process that co-processes renewable biomass with petroleum. We are also finalizing our proposed definition of ''canola/rapeseed oil'' and adding this definition to 40 CFR 80.1401.

II. Review and Response to Comments on the Notice of Proposed Rulemaking

A. Comments Received on Our Lifecycle Analysis

EPA requested comment on its lifecycle analysis of the GHG emissions associated with renewable diesel, jet fuel, naphtha, LPG, and heating oil produced from canola oil via a hydrotreating process.

Several commenters expressed support for our lifecycle analysis. Commenters supported EPA's new modeling of canola oil-based fuels using updated data on canola and canola products.[8] Commenters also expressed that EPA's updated modeling of international canola market conditions better simulates and reflects the behavior of the historical and current global canola trade, in particular the

[2] For additional information see: *https://www.epa.gov/renewable-fuel-standard-program/fuel-pathways-under-renewable-fuel-standard*.

[3] See, *e.g.,* 83 FR 37735 (August 2, 2018) approving grain sorghum oil pathways and 78 FR 41703 (July 11, 2013) approving giant reed and Napier grass pathways.

[4] 42 U.S.C. 7545(o)(1)(H).

[5] Hydrotreating, the process used to produce the vast majority of renewable diesel, consists of catalytic reactions in the presence of hydrogen. This process produces a ''drop-in'' fuel with properties virtually identical to petroleum diesel and distinct from biodiesel.

[6] U.S. Canola Association. (2020). Petition for Pathways for Renewable Diesel from Canola Oil as ''Advanced Biofuel'' Under the Renewable Fuel Standard Program. EPA–HQ–OAR–2021–0845–0040.

[7] The full set of modeling results, post-processing spreadsheets and other technical documents describing this analysis are available in the docket for this action.

[8] See Docket Item No. EPA–HQ–OAR–2021–0845–0053, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0057, EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0068, EPA–HQ–OAR–2021–0845–0069.

dynamics between the U.S. and Canada.[9] Commenters did not provide any comments on this analysis that indicate it is unreasonable to rely on it for this rulemaking, such as the presence of errors in the analysis, the use of outdated data, or any other scientific deficiencies that might require EPA to conduct new analysis before finalizing our determination. Some commenters stated that EPA's analysis may be overly conservative in the sense that, in the opinion of these commenters, our analysis may overstate the GHG intensity of canola oil-based fuels. Multiple commenters claimed that U.S. canola producers may be able to expand canola production on fallow land or Conservation Reserve Program (CRP) land, or make changes to crop rotations, to provide additional canola seed and oil for biofuel feedstock supply without the need for cultivation of new crop area. Commenters argued that, for these reasons EPA's estimated cropland change emissions impacts may be too high.[10] However, these commenters did not provide data or information that would support specific revisions in our modeling. Regardless, revising our analysis in the manner suggested by these commenters would not materially affect the results of our determination for these canola oil pathways. Since we proposed to determine that the pathways in question be approved to generate RINs under the most valuable renewable fuel categories (*i.e.,* the advanced biofuel and/or BBD pathways) for which they are eligible, further reductions in LUC emissions, were a revised analysis to find such a result, would lead to the same pathway determination. Finally, commenters who made these points did not state that revisions should be made to EPA's analysis before finalizing the proposed pathways. Rather, these commenters instead uniformly supported the finalization of EPA's analysis and determination as proposed. For all of these reasons, we believe no revisions to our lifecycle analysis are appropriate or necessary in response to these comments.

Commenters supported our inclusion of pathways for fuels produced from co-processing canola oil with petroleum feedstocks, *i.e.,* co-processed fuels.[11] In their comments, Phillips 66 suggested additional data sources about the emissions associated with co-processing of canola oil via hydrotreating, which EPA could consider if needed. However, neither Phillips 66 nor any other commenter who addressed co-processing suggested that any revision of this aspect of our analysis was needed. Further, revising our analysis to consider the additional data provided by Phillips 66 would not materially affect the results of our determination for these canola oil pathways. We believe no revisions to our lifecycle analysis are appropriate or necessary in response to these comments.

The American Petroleum Institute (API) observed that lifecycle analysis methodology was the focus of a recent EPA workshop on biofuel GHG modeling.[12] API expressed support for the efforts of EPA to consider new science and data in the context of biofuel lifecycle analysis. However, API also expressed that the scientific discussions at this workshop should not necessitate any revisions to the analysis conducted for the Canola NPRM. Rather, this commenter stated that any such revisions should be considered in the future in the context of more holistic re-examination of RFS pathways, so that they can be applied consistently across all approved pathways.[13] EPA did not propose to apply a new lifecycle analysis methodology to canola oil, and we are not doing so in this final rule. Any decisions EPA may make about future lifecycle analyses and determinations are outside the scope of this rulemaking.

In the proposed rule we requested comment on our proposed use of an energy allocation approach to evaluate co-products from hydrotreating processes (87 FR 22838). We received two comments on this topic.[14] One of the commenters said they agree with EPA's reasoning and support the energy allocation approach taken. The other commenter did not oppose EPA's use of energy allocation, but believes it is a conservative approach that may not be appropriate in all cases. Based on these comments, and the reasons given in the proposed rule, we are retaining the proposed energy allocation approach to the evaluation of the co-products from hydrotreating processes. Furthermore, for the reasons discussed in the proposed rule, we believe that energy allocation is generally the most appropriate approach for co-products that may be used as transportation fuel. Unlike the displacement approach, the allocation approach does not depend on which co-products generate RINs (or for which producers request RIN eligibility), which is subject to change based on market and regulatory conditions.

We have determined that no changes to our proposed lifecycle analysis of the GHG emissions associated with renewable diesel, jet fuel, naphtha, LPG, and heating oil produced from canola oil via a hydrotreating process are necessary or appropriate based on the public comments received. However, as discussed in section IV of this action, we are updating emission factors from GREET–2020 to GREET–2021, consistent with our intention as expressed in the Canola NPRM preamble. Further information on our lifecycle analysis is available in the Canola NPRM preamble [15] and the docket for this rulemaking.[16]

B. Other Comments Received on Our Proposed Pathway Determinations

EPA received other comments on our determination that renewable diesel, jet fuel, naphtha, LPG, and heating oil meet the 50 percent GHG reduction threshold required for advanced biofuel and BBD, but these comments did not directly address our lifecycle analysis of the proposed canola oil pathways. These comments are summarized below.

Several commenters expressed general support for the finalization of our proposed determination. Commenters associated with the canola production and processing industries expressed an ability to provide feedstock to the biofuel industry to produce fuels under the proposed canola oil pathways.[17] Commenters argued that approval of these pathways would provide several economic and societal benefits, including supporting rural economies,[18] reducing U.S. GHG emissions,[19] providing greater feedstock diversity to the biofuel industry (particularly for renewable diesel and jet fuel),[20] and reducing reliance on

[9] See Docket Item No. EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0072.

[10] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0053, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0063, EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0076.

[11] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0079.

[12] For information regarding this workshop, see Docket No. EPA–HQ–OAR–2021–0921.

[13] See Docket Item No. EPA–HQ–OAR–2021–0845–0058.

[14] Docket Item No. EPA–HQ–OAR–2021–0845–0079 and EPA–HQ–OAR–2021–0845–0072.

[15] See 87 FR 22826–40.

[16] See Docket No. EPA–HQ–OAR–2021–0845.

[17] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0052, EPA–HQ–OAR–2021–0845–0053, EPA–HQ–OAR–2021–0845–0055.

[18] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0053, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0068.

[19] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0053, EPA–HQ–OAR–2021–0845–0054, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0062, EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0068.

[20] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0054, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0057, EPA–HQ–OAR–2021–0845–0062, EPA–HQ–OAR–2021–0845–0065, EPA–HQ–OAR–2021–0845–0068.

imported petroleum.[21] Commenters also stated that the lack of a renewable diesel pathway in particular has been an impediment to the canola industry and that approval of this pathway would provide a more level playing field with other renewable diesel feedstocks.[22]

Several commenters supported our proposed determination that no invasive species-related risk management measures are appropriate in the context of these canola oil pathways. The Minnesota Canola Council stated in their comments that ''[c]anola has been grown throughout the U.S. for decades without posing invasiveness concerns''.[23] Other comments addressing the topic of canola invasiveness potential concurred with this statement.[24] We did not receive comment suggesting that canola has any significant potential to become invasive in the United States, nor did any commenters suggest that risk management measures would be appropriate for these canola oil pathways.

Airlines for America provided comments observing that EPA's proposed revisions to the RFS regulations included certain minor technical errors.[25] Specifically, according to the proposed regulations included in the Canola NPRM, the term ''Distillers corn oil'' would be deleted and replaced with ''Non-food grade corn oil'' and ''Commingled distillers corn oil and sorghum oil'' would be deleted entirely from the feedstock column in row H. These changes were unintentional errors. Airlines for America acknowledged in their comments that these errors were likely unintentional and requested that EPA clarify in the preamble of the final rule that this is the case. We clarify here that these proposed changes were in fact unintentional errors. EPA is not finalizing these changes to the regulations.

EPA received comments from the Pet Food Institute (PFI) opposing the proposed pathway on the grounds that approving these canola oil-based pathways would create additional financial hardship for PFI's member companies, for whom vegetable oils are an important product input. In their comments, PFI observed that prices for vegetable- and animal-based fats, oils, and greases (FOG) are presently high in 2022. They argued that approving these pathways would create additional upward pressure on FOG prices and reduce FOG availability for their member companies.[26] These comments mirrored similar comments submitted by PFI on a separate recent RFS rulemaking, namely the Proposed RFS Standards for 2020, 2021, and 2022.[27] EPA's Response to Comment (RTC) document associated with that rulemaking addresses these comments in the broader context of RFS program impacts on FOG availability and prices, inclusive of impacts attributable to canola oil-based fuels.[28] As was discussed in this earlier RTC document, EPA recognizes that prices for these FOG commodities have been relatively high in 2022. However, we also note that several companies, including both renewable diesel producers and other parties, have already begun to respond to this price signal by announcing investment in increased vegetable oil refining capacity.[29] Thus, we believe that the market is adjusting to supply the necessary volumes of refined vegetable oil to both the biofuel and food markets, and we do expect that both human and animal food producers will be able to acquire the refined vegetable oil they need in 2022 and future years. In addition, aggregate demand for vegetable oil-based fuels under the RFS program is primarily a function of the annual Renewable Volume Obligations (RVOs), not any individual pathway approval. To the extent that any FOG price impacts may be associated with demand created by the RFS program, EPA believes such impacts would be associated with the decisions about the levels at which RVOs are set, not approvals of individual fuel pathways. PFI does not present evidence that approving additional fuel pathways in and of itself will cause a direct increase in overall consumption of biofuels under the RFS program or cause an increase in FOG prices and we do not believe such outcomes will result from this action. Additionally, several commenters on the Canola NPRM argued the opposite, *i.e.,* that approval of these pathways is likely to create additional flexibility for biofuel producers, increase economic efficiency, and reduce prices.[30] In general, we agree that creating additional flexibility under the RFS program is likely to, if anything, reduce feedstock prices.

Finally, CAA section 211(o)(1) contains the exclusive considerations for evaluating whether a fuel qualifies as BBD or advanced biofuel. As further explained in the response to comments regarding the Endangered Species Act (ESA) below, the statute provides that EPA consider whether the fuel meets the definition of renewable fuel (produced from renewable biomass and used to replace or reduce the quantity of fossil fuel present in a transportation fuel), whether it provides the qualifying lifecycle greenhouse gas reduction as compared to baseline petroleum fuel, and whether the biomass is co-processed with petroleum feedstocks (see CAA section 211(o)(1)(D)). The statutory definitions and scheme leave EPA no discretion to decline to qualify a biofuel as BBD or advanced biofuel under the RFS program based on additional considerations that are not identified in the statute, such as price impacts on canola-oil feedstocks. These factors, again, represent the full range of considerations that EPA is authorized to consider in determining whether a fuel qualifies as BBD or advanced biofuel. In light of this carefully constrained statutory scheme, EPA is without authority to alter this rule based on vegetable oil price considerations, and EPA has no discretion to deny approval of this pathway if the statutory criteria are met. As noted above, to the extent any FOG price impacts may be associated with demand created by the RFS program, we believe such impacts would be associated with decisions made about the levels at which the RVOs are set, not approvals of individual fuel pathways. Thus, we consider PFI's comments outside the scope of this action.

EPA received comments from the Center for Biological Diversity (CBD) opposing our proposed determination on the grounds that approval of this pathway would increase the production of canola to meet new biofuel demands, which would in turn allegedly cause harmful effects for a least five species [31]

[21] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0062, EPA–HQ–OAR–2021–0845–0070.

[22] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0069.

[23] See Docket Item No. EPA–HQ–OAR–2021–0845–0053.

[24] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0063, EPA–HQ–OAR–2021–0845–0066, EPA–HQ–OAR–2021–0845–0072.

[25] See Docket Item No. EPA–HQ–OAR–2021–0845–0065.

[26] Docket Item No. EPA–HQ–OAR–2021–0845–0077.

[27] 86 FR 72436–501. PFI's comments are available on the docket for this rulemaking, Docket No. EPA–HQ–OAR–2021–0324–0453.

[28] See Section 4.2, Renewable Fuel Standard (RFS) Program: RFS Annual Rules—Response to Comments, EPA–420–R–22–009, June 2022.

[29] Id.

[30] See, *e.g.,* Docket Item No. EPA–HQ–OAR–2021–0845–0054, EPA–HQ–OAR–2021–0845–0055, EPA–HQ–OAR–2021–0845–0057, EPA–HQ–OAR–2021–0845–0062, EPA–HQ–OAR–2021–0845–0065, EPA–HQ–OAR–2021–0845–0068.

[31] The comments identify these species as the Pallid Sturgeon (*Scaphirhynchus albus*), the Whooping Crane (*Grus americana*), the Dakota

Continued

listed under the ESA. CBD argues that these alleged effects would cross the ''may effect'' and/or ''likely to adversely affect'' thresholds relevant to ESA considerations and thus trigger consultation requirements under the ESA and its implementing regulations. They state that EPA's approval of the proposed canola oil pathways represents a discretionary programmatic action. On this basis, CBD argues EPA must therefore consult with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (hereinafter collectively referred to as ''the Services'') under section 7 of ESA before finalizing these canola oil pathways.

Contrary to CBD's assertions, for this action, we find that EPA lacks discretion to disapprove this pathway petition on the basis of impacts to listed species or designated critical habitat of such species. Section 7(a)(2) of the ESA requires federal agencies, in consultation with one or both of the Services, to ensure that actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of federally listed endangered or threatened species or result in the destruction or adverse modification of designated critical habitat of such species.[32] Under relevant implementing regulations and case law, section 7(a)(2) applies only to actions where there is discretionary federal involvement or control.[33]

In *Defenders of Wildlife,* the Supreme Court evaluated a claim that EPA was required to engage in section 7 consultation in the context of its approval of a state permitting program under the Clean Water Act (CWA). In that case, the Court held that when a Federal agency is required by statute to undertake a particular action without considering species impacts, there is no relevant agency discretion, and thus the requirements of ESA section 7(a)(2) do not apply.[34] With regard to EPA's transfer of CWA permitting authority to a State, the relevant CWA provision specified that EPA ''shall approve'' a state permitting program if a list of CWA statutory criteria are met. The Court found that the relevant CWA program approval criteria did not include consideration of endangered or threatened species and stated that ''[n]othing in the text of [the relevant CWA provision] authorizes EPA to consider the protection of threatened or endangered species as an end in itself when evaluating [an] application'' to transfer a permitting program to a State.[35] Accordingly, the Court held that the CWA required EPA to approve the state's permitting program if the statutory criteria were met; those criteria did not include the consideration of ESA-protected species; and thus, consistent with 50 CFR 402.03, the nondiscretionary action to transfer CWA permitting authority to the state did not trigger ESA section 7 consultation requirements.

Similar to the CWA program approval provision at issue in *Defenders of Wildlife,* the CAA contains detailed provisions specifying the parameters of fuels that qualify under this regulatory program.[36] None of those provisions provide EPA the discretion to modify its evaluation of potential qualifying fuels based on extra-statutory criteria. Of relevance here, the CAA includes detailed definitions of the terms ''advanced biofuel'' and ''biomass-based diesel,'' and those definitions do not allow for consideration of impacts to threatened or endangered species in this action.

Advanced biofuel is defined as ''renewable fuel, other than ethanol derived from corn starch, that has lifecycle greenhouse gas emissions, as determined by the Administrator, after notice and opportunity for comment, that are at least 50 percent less than baseline lifecycle greenhouse gas emissions.'' [37] This definition includes defined terms within it, including the terms ''renewable fuel,'' (''[f]uel that is produced from renewable biomass and that is used to replace or reduce the quantity of fossil fuel present in a transportation fuel''), ''baseline lifecycle greenhouse gas emissions'' (''average lifecycle greenhouse gas emissions . . . for gasoline or diesel . . . sold or distributed as transportation fuel in 2005''), and ''lifecycle greenhouse gas emissions''. The term ''lifecycle greenhouse gas emissions'' means the aggregate quantity of greenhouse gas emissions (including direct emissions and significant indirect emissions such as significant emissions from land use changes), as determined by the Administrator, related to the full fuel lifecycle, including all stages of fuel and feedstock production and distribution, from feedstock generation or extraction through the distribution and delivery and use of the finished fuel to the ultimate consumer, where the mass values for all greenhouse gases are adjusted to account for their relative global warming potential.[38]

Thus, in determining if a fuel qualifies as advanced biofuel, EPA must consider whether it meets the definition of renewable fuel—that is, whether it is made from ''renewable biomass'' as defined in the statute and is ''used to replace or reduce the quantity of fossil fuel present in transportation fuel.'' EPA must also consider whether a fuel is made from corn starch, and whether it satisfies the requirement that it achieve a 50 percent lifecycle GHG emissions reduction as compared to baseline lifecycle greenhouse gas emissions. These factors represent the full range of considerations that EPA is authorized to consider in determining whether a fuel qualifies as advanced biofuel; it follows that EPA is not authorized to consider impacts to threatened or endangered species in determining what fuels qualify as advanced biofuels under the CAA. In light of this carefully constrained statutory scheme, EPA is without authority to alter this rule based on listed species considerations and is under no obligation to consult with the Services under section 7(a) of the ESA with respect to the advanced biofuel pathways established in this action that utilize canola oil feedstock to produce renewable diesel. EPA has no discretion to deny approval of this pathway if the statutory criteria are met.

The same is true with respect to the pathways approved in this action for the production of BBD from canola oil. The term biomass-based diesel is defined in the CAA as renewable fuel that is biodiesel as defined in section 13220(f) of this title and that has lifecycle greenhouse gas emissions . . . that are at least 50 percent less than the baseline lifecycle greenhouse gas emissions. Notwithstanding the preceding sentence, renewable fuel derived from co-processing biomass with a petroleum feedstock shall be advanced biofuel if it meets the requirements of [42 U.S.C. 7545(o)(1)(B)], but is not biomass-based diesel.[39]

The term ''biodiesel'' is defined in 42 U.S.C. 13220(f) to mean ''a diesel fuel substitute produced from nonpetroleum renewable resources that meets the registration requirements for fuels and fuel additives established by the Environmental Protection Agency under section 211 of the Clean Air Act [42 U.S.C. 7545]'' and ''includes biodiesel derived from—(i) animal wastes, including poultry fats and poultry

Skipper (*Hesperia dacotae*), the Western Prairie Fringed Orchid (*Platanthera praeclara*) and the Poweshiek Skipperling (*Oarisma poweshiek*).

[32] 16 U.S.C. 1536(a)(2).

[33] 50 CFR 402.03; *National Ass'n of Home Builders* v. *Defenders of Wildlife,* 127 S. Ct. 2518 (2007) (*Defenders of Wildlife*).

[34] *Defenders of Wildlife* at 2536.

[35] Id. at 2537.

[36] 42 U.S.C. 7545(o)(1).

[37] 42 U.S.C. 7545(o)(1)(B).

[38] 42 U.S.C. 7545(o)(1)(J), (H).

[39] 42 U.S.C. 7545(o)(1)(D).

wastes, and other waste materials; or (ii) municipal solid waste and sludges and oils derived from wastewater and the treatment of wastewater.'' Thus, in evaluating whether a fuel qualifies as BBD, EPA is authorized to consider only whether the fuel meets the definition of renewable fuel (made from renewable biomass and used to replace or reduce the quantity of fossil fuel present in a transportation fuel), whether it provides a qualifying lifecycle GHG reduction as compared to baseline petroleum fuel, whether the biomass is co-processed with petroleum feedstocks, and whether it meets the registration requirements for fuels and fuel additives established via rulemaking by EPA. These factors, again, represent the full range of considerations that EPA is authorized to consider in determining whether a fuel qualifies as BBD; it follows that EPA is not authorized to consider impacts to threatened or endangered species in determining what fuels qualify as BBD under the CAA. In light of this carefully constrained statutory scheme, EPA is without authority to alter this rule based on listed species considerations and is under no obligation to consult with the Services under section 7(a) of the ESA with respect to the advanced biofuel pathways established in this action that utilize canola oil feedstock to produce BBD. EPA has no discretion to deny approval of this pathway if the statutory criteria are met.

The action EPA is taking today is to determine that renewable diesel, jet fuel, heating oil, naphtha, and LPG produced from canola oil via a hydrotreating process meet the applicable statutory requirements and thus qualify as renewable fuels under the RFS program. EPA is not establishing volume requirements, which would require the use of renewable fuel of various quantities and types (without requiring any particular type of renewable fuel). EPA is currently engaged in consultation with the Services on renewable fuel standards and will consider the future use of canola oil under the RFS program in that context. As discussed in response to comments from PFI, it is the RFS standards that could impact demand for advanced biofuel and biomass-based diesel; this pathway approval simply provides an additional opportunity and flexibility that renewable fuel producers may choose to adopt. Additionally, through the ongoing consultation process, EPA will consider any impacts on species and designated critical habitat as a result of our action setting RFS standards, including any impacts associated with the use of canola oil to produce renewable fuel within the RFS program, and will also consider any appropriate responses.

III. Definition of Canola/Rapeseed Oil

EPA received comments on its proposed definition of ''canola/rapeseed oil.'' Joint comments from three Canadian canola industry organizations expressed that they believe ''canola and rapeseed are well understood crops in the United States'' and that, therefore, they ''do not believe definitions are necessary.'' [40] However, these commenters also stated that they ''do not necessarily take issue with the proposed definitions, which [they] believe identify the key species being used for canola production in Canada today, so long as EPA makes clear that it does not intend to impose additional requirements on farmers or feedstock providers and that these terms are only intended to be descriptors to distinguish canola and rapeseed based on the distinct treatment of these crops in the U.S.'' [41] The USCA expressed similar opinions in their comments. While they believe the relevant market participants fully understand the meaning of ''canola oil,'' and that, therefore, no definition in the regulations is necessary, USCA also expressed that they do not oppose the addition of this definition to the regulations.[42]

To clarify, EPA has not proposed, nor are we finalizing, any new registration, recordkeeping, or reporting requirements associated with implementing the canola oil-based pathways or our new definition of canola/rapeseed oil. We are including this definition in the regulations to provide clarity regarding which vegetable oil products qualify under this pathway. This intent is well-aligned with that described by the commenters. We are finalizing the definition largely as proposed, with one minor, clerical edit for readability.

IV. Analysis of Lifecycle GHG Emissions

A. Overview of Lifecycle GHG Emissions Analysis

For the proposed rule, we evaluated the lifecycle GHG emissions of producing renewable diesel and other biofuels from canola oil through a hydrotreating process. We described our methodology for conducting this evaluation, the assumptions and scenarios evaluated using this methodology, and the results of our analysis. We used the same biofuel lifecycle analysis methodology and modeling framework developed for the March 2010 RFS2 rule, which was adopted after an extensive peer review and public comment process. This methodology was developed to estimate ''lifecycle greenhouse gas emissions'' as defined in CAA section 211(o)(1)(H). The same methodology and modeling framework were subsequently used for the September 2010 Canola Oil Rule.[43] The components of this methodology generally involve the use of agricultural modeling to estimate emissions from land use change, crop production, livestock, and rice methane, as well as application of coefficients and assumptions from the Greenhouse Gases, Regulated Emissions, and Energy use in Technologies (GREET) model [44] and other sources to evaluate emissions associated with feedstock and fuel transport, processing, and use.

In general, this methodology also involves using two agricultural sector models, FASOM and the FAPRI–CARD model, to estimate U.S. and non-U.S. GHG emissions impacts, respectively. Applying our methodology in the analysis conducted for the Canola NPRM, we modeled and evaluated a hypothetical canola oil demand shock scenario to estimate changes in agricultural production and land use and associated GHG emissions associated with the biofuel pathways under consideration. In the demand shock scenario modeled for our Canola NPRM analysis, U.S. domestic consumption of canola oil-based fuels was assumed to increase by some amount relative to the volume of U.S. domestic consumption in a reference scenario.

This methodology also includes estimating GHG emissions associated with fuel production, distribution and use based on data from GREET and other sources. All of these GHG emissions estimates are added together and divided by the change in the amount of biofuel produced in the scenarios evaluated to estimate the lifecycle GHG emissions associated with fuel produced through the evaluated pathway, in terms of carbon dioxide-equivalent emissions per megajoule (MJ) of fuel produced.

[40] Docket Item No. EPA–HQ–OAR–2021–0845–0066.

[41] Id.

[42] Docket Item No. EPA–HQ–OAR–2021–0845–0072.

[43] For information about our 2010 methodology and analysis see section 2 of the regulatory impact analysis (RIA) for the March 2010 RFS2 rule and the associated lifecycle results (Docket Item No. EPA–HQ–OAR–2005–0161–3173).

[44] See documentation and description available from Argonne National Lab at *https://greet.es.anl.gov.*

We stated in section II.C.1 of the Canola NPRM that we would update emissions factor assumptions from GREET–2020 to GREET–2021 for the final rule. We received no public comment on this statement or our intention to update to GREET–2021 for the final rule. We have made these updates for the final rule and describe the impacts of these updates below.

Other than updating particular emissions factors based on GREET–2021 as we committed to do in the proposed rule, we are finalizing our lifecycle GHG analysis as proposed. Detailed information and discussion regarding the other components of our methodology is available in the Canola NPRM preamble [45] and the docket for this rulemaking.[46] We summarize the results of our updated lifecycle analysis in section IV.C below.

B. Data Updates Based on GREET–2021

Based on the lifecycle analysis methodology developed for the March 2010 RFS2 rule, our analysis uses data from the GREET model on the emissions per unit of energy or mass associated with particular inputs to the product lifecycle (''emissions factors''). These emissions factors are the estimates from GREET associated with using inputs such as diesel, electricity, and natural gas. In the proposal we said that we would update these data based on GREET–2021, and that we did not expect these updates to have a large enough effect on the lifecycle GHG emissions estimates to change our GHG reduction threshold determinations for the proposed canola oil-based fuel pathways. We have made the data updates based on GREET–2021 and as expected these updates have a relatively small effect on our lifecycle GHG estimates.[47]

The GREET data updates were applied to the following elements: emissions factors for the production and use of gasoline, diesel, natural gas, LPG, coal, gaseous hydrogen, electricity, fertilizer, herbicide, and insecticide. The emissions factors increased for gasoline, diesel, natural gas, LPG, fertilizer, and pesticide.[48] The emissions factors decreased for gaseous hydrogen, electricity, limestone, and herbicide. Overall, these updates changed our lifecycle GHG estimates by less than two percent. For canola oil renewable diesel, we now estimate GHG reductions of 64–70 percent relative to the baseline, compared to 63–69 percent in the proposal. For canola oil-based naphtha and LPG we estimate GHG reductions of 63–69 percent, unchanged from the proposal. For canola oil-based renewable jet fuel we estimate GHG reductions of 58–67 percent, compared to 59–67 percent in the proposal.

C. Summary of Analysis of Lifecycle GHG Emissions

Table IV.C–1 reports our estimates of the lifecycle GHG emissions associated with renewable diesel produced from canola oil through a hydrotreating process, and the corresponding percent reduction relative to the petroleum baseline. Three sets of estimates are presented for canola oil renewable diesel. The emissions categories are aggregated to simplify the presentation of the table. Domestic and international agricultural emissions include emissions associated with changes in crop and livestock production. Feedstock processing (*i.e.,* canola seed crushing) and feedstock seed and oil transport emissions are reported together. Downstream and use includes emissions from fuel distribution and fuel use. Land use change emissions include emissions from domestic and international land use changes, including both emissions from direct conversion to cropland and market-mediated effects such as foregone potential land carbon sequestration. As discussed in section IV.B, we have made minor updates relative to the proposed rule by incorporating more recent emissions factors from the GREET–2021 model. These updates changed our GHG estimates in the tables below for the feedstock transport & crushing, fuel production, and downstream & use lifecycle stages. All other estimates remain unchanged from the NPRM.

Our evaluation considers uncertainty in international land use change emissions based on the methodology used for the March 2010 RFS2 rule. The table includes a range of land use change estimates based on our analysis of this uncertainty. The first column includes results based on our average estimate of international land use change GHG emissions. We also report results for the low and high ends of our 95 percent confidence interval for international land use change emissions. Our calculations include ranges for domestic agriculture, international agriculture, feedstock transport and crushing, and fuel production are based on estimated ranges in the yield of finished fuel (in MJ of fuel produced per pound of canola oil feedstock). However, to simplify the presentation of the results we report the average of the eight estimates.[49]

Another update is that the analysis for the March 2010 RFS2 rule used 100-year global warming potential (GWP) values from the IPCC Second Assessment Report. The analysis for this proposed rule uses 100-year GWP values from the most recent IPCC Fifth Assessment Report.[50] Based on these updates, the GWP for methane increased from 21 to 30, and the GWP for nitrous oxide decreased from 310 to 265. This update was described in section II.C.1 of the NPRM; we did not receive public comment on this update.

TABLE IV.C–1–LIFECYCLE GHG EMISSIONS ASSOCIATED WITH RENEWABLE DIESEL PRODUCED FROM CANOLA OIL THROUGH A HYDROTREATING PROCESS

[In grams of CO_2 equivalent per MJ]

Emissions category	2005 Diesel baseline	Canola oil renewable diesel
Domestic Agriculture	18	−2.3
International Agriculture		−0.3
Feedstock Transport & Crushing		6.9
Fuel Production		12.4

[45] See 87 FR 22826–40.

[46] See Docket No. EPA–HQ–OAR–2021–0845.

[47] The lifecycle GHG calculations including the updated GREET emissions factors are included in a spreadsheet available in the docket for this action.

[48] We corrected an underestimate in the proposed rule of the GHG emissions associated with crude oil extraction.

[49] Using the average or median values results in the same percent GHG reduction relative to the petroleum baseline. We are not taking a position on whether it is more appropriate to use mean or median values in other contexts.

[50] IPCC, 2014: Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Core Writing Team, R.K. Pachauri and L.A. Meyer (eds.)]. IPCC, Geneva, Switzerland, 151 pp.

TABLE IV.C–1–LIFECYCLE GHG EMISSIONS ASSOCIATED WITH RENEWABLE DIESEL PRODUCED FROM CANOLA OIL THROUGH A HYDROTREATING PROCESS—Continued

[In grams of CO_2 equivalent per MJ]

		0.4		
Downstream & Use	75			
Land Use Change Estimate	.....	Mean	Low	High
Land Use Change	.....	13.8	3.2	26.0
Net Emissions	93	30.9	20.2	43.1
% GHG Reduction Relative to Baseline	.....	67%	78%	53%

In many cases, when vegetable oils are hydrotreated to produce renewable diesel, there are co-product outputs of naphtha, LPG, and jet fuel. The GHG estimates for these co-product fuels differ slightly from the renewable diesel estimates presented in the table above based on differences in how they are transported to end users and in end use emissions. The results for naphtha and LPG, based on the mean international land use change estimates, are summarized in Table IV.C–2.

TABLE IV.C–2—LIFECYCLE GHG EMISSIONS ASSOCIATED WITH NAPHTHA AND LPG PRODUCED FROM CANOLA OIL THROUGH A HYDROTREATING PROCESS

[In grams of CO_2 equivalent per MJ]

	Naphtha	LPG
Lifecycle GHG Emissions	31.4	31.4
Percent Reduction Relative to Baseline	67%	66%

We do not present separate results of heating oil as it is not reported as an output for any of the hydrotreating processes evaluated. However, renewable diesel could be used as heating oil if market conditions change substantially (*e.g.,* if heating oil prices were to exceed diesel prices net of government incentives). The GHG emissions associated with heating oil are therefore very similar to renewable diesel, although there may be small differences in GHG emissions associated with fuel distribution and use.

As discussed in the NPRM,[51] canola oil hydrotreating processes that are set up to maximize jet fuel output require more processing and hydrogen, resulting in greater lifecycle GHG emissions. The range of lifecycle GHG estimates for canola oil renewable jet fuel are reported in Table IV.C–3.

TABLE IV.C–3—LIFECYCLE GHG EMISSIONS ASSOCIATED WITH RENEWABLE JET FUEL PRODUCED FROM CANOLA OIL THROUGH A HYDROTREATING PROCESS

[in grams of CO_2 equivalent per MJ]

Emissions category	2005 diesel baseline	Canola oil renewable jet fuel		
Domestic Agriculture	18	−2.3		
International Agriculture	.....	−0.3		
Feedstock Transport & Crushing	.....	6.8		
Fuel Production	.....	15.4		
		0.4		
Downstream & Use	75	.....		
Land Use Change Estimate		Mean	Low	High
Land Use Change (LUC)		13.7	3.1	25.9
Net Emissions	93	33.8	23.2	46
% GHG Reduction Relative to Baseline		63%	75%	50%

V. Summary

Based on our GHG lifecycle evaluation described in the NPRM, we find that renewable diesel, jet fuel, naphtha, LPG, and heating oil produced from canola oil via a hydrotreating process all meet the 50 percent GHG reduction threshold. Based on this finding, we determine that renewable diesel, jet fuel, and heating oil produced from canola oil are eligible for BBD (D–code 4) RINs if they are produced through a hydrotreating process that does not co-process renewable biomass and petroleum, and for advanced biofuel (D–code 5) RINs if they are produced through a process that does co-process renewable biomass and petroleum. Based on this finding, we also determine that naphtha and LPG production from canola oil through a hydrotreating process are eligible for advanced biofuel (D–code 5) RINs. Based on these determinations, we are adding these pathways to Table 1 of 40 CFR 80.1426.

We are also finalizing our proposed definition of ''canola/rapeseed oil'' and adding this definition to 40 CFR 80.1401.

VI. Statutory & Executive Order Reviews

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

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response

[51] See 87 FR 22838 for details.

to OMB recommendations have been documented in the docket. The GHG lifecycle analysis conducted for this proposed determination, ''Renewable Fuel Standard Program: Canola Oil Pathways to Renewable Diesel, Jet Fuel, Naphtha, Liquefied Petroleum Gas and Heating Oil,'' is available in the docket.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060–0725. This action creates new pathways by which to generate RINs for renewable fuels under the RFS program but creates no new information collection requirements for these additional pathways.

C. Regulatory Flexibility Act (RFA)

I certify that this action does not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the agency is certifying that this rule would not have a significant economic impact on a substantial number of small entities if the rule would have no net burden. This rule enables canola oil producers and producers of biofuels from canola oil to participate in the RFS program if they choose to do so to obtain economic benefits. We have therefore concluded that this action has no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action 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 does 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 does not have tribal implications as specified in Executive Order 13175. This rule affects only producers of canola oil and producers of biofuels made from canola oil. Thus, Executive Order 13175 does not apply to this action.

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

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

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule enables canola oil producers and producers of biofuels from canola oil to participate in the RFS program if they choose to do so. This may create additional supplies of energy, potentially leading to positive impacts on the energy system. This rule would create no new burdens on the distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This rule gives renewable fuel producers the ability to generate credits under the RFS program for the production of specified biofuels from canola oil. This rule does not affect the level of protection provided to human health or the environment by applicable air quality standards. EPA recognizes that the RFS program as a whole may have impacts related to environmental justice. These potential impacts are discussed further in the RFS Annual Rules for 2020, 2021, and 2022, published in June 2022.[52] Future actions to set biofuel volume requirements may take into consideration the availability of this renewable fuel pathway for the production of biofuel from canola oil and thus may affect GHG emissions, air quality, water or soil quality, or fuel and food prices.[53] However, this action does not modify biofuel volume requirements and thus EPA believes that the final rule to approve a new pathway, in and of itself, will not affect human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VII. Statutory Authority

Statutory authority for this action comes from CAA sections 114, 208, 211, and 301.

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Diesel fuel, Fuel additives, Gasoline, Imports, Oil imports, Petroleum, Renewable fuel.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 80 as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

Subpart M—Renewable Fuel Standard

■ 2. Amend § 80.1401 by adding in alphabetical order a definition for ''Canola/Rapeseed oil'' to read as follows:

§ 80.1401 Definitions.

* * * * *

Canola/Rapeseed oil means either of the following:

(1) *Canola oil* is oil from the plants *Brassica napus, Brassica rapa, Brassica juncea, Sinapis alba,* or *Sinapis arvensis* and which typically contains less than

[52] See 87 FR 39600–77 and Chapter 8, Renewable Fuel Standard (RFS) Program: RFS Annual Rules—Regulatory Impact Analysis, EPA–420–R–22–008, June 2022.

[53] Id.

2 percent erucic acid in the component fatty acids obtained.

(2) *Rapeseed oil* is the oil obtained from the plants *Brassica napus, Brassica rapa,* or *Brassica juncea.*

* * * * *

■ 3. Amend § 80.1426 in table 1 to § 80.1426 by revising the entries ''G'', ''H'', and ''I'' to read as follows:

§ 80.1426 How are RINs generated and assigned to batches of renewable fuel?

* * * * *

TABLE 1 TO § 80.1426—APPLICABLE D CODES FOR EACH FUEL PATHWAY FOR USE IN GENERATING RINS

	Fuel type	Feedstock	Production process requirements	D–Code
*	*	*	*	*
G	Biodiesel, renewable diesel, jet fuel, and heating oil.	Canola/Rapeseed oil	One of the following: Transesterification using natural gas or biomass for process energy, or Hydrotreating; excludes processes that co-process renewable biomass and petroleum.	4
H	Biodiesel, renewable diesel, jet fuel, and heating oil.	Soy bean oil; Oil from annual covercrops; Oil from algae grown photosynthetically; Biogenic waste oils/fats/greases; *Camelina sativa* oil; Distillers corn oil; Distillers sorghum oil; Commingled distillers corn oil and sorghum oil; Canola/Rapeseed oil.	One of the following: Transesterification with or without esterification pre-treatment, Esterification, or Hydrotreating; includes only processes that co-process renewable biomass and petroleum.	5
I	Naphtha, LPG	*Camelina sativa* oil; Distillers sorghum oil; Distillers corn oil; Commingled distillers corn oil and distillers sorghum oil; Canola/Rapeseed oil.	Hydrotreating	5
*	*	*	*	*

* * * * *

[FR Doc. 2022–26250 Filed 12–1–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 123

[EPA–HQ–OW–2022–0834; FRL–10123–02–OW]

RIN 2040–AG27

NPDES Small MS4 Urbanized Area Clarification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to clarify its National Pollutant Discharge Elimination System (NPDES) Stormwater Phase II regulations due to recent changes made by the Census Bureau. The changes to EPA's regulations are limited to clarifying that the designation criteria for small municipal separate storm sewer systems (MS4s), which have been used since the promulgation of the regulations in 1999, will remain the same. These clarifications are necessary due to the Census Bureau's recent decision to discontinue its practice of publishing the location of ''urbanized areas'' along with the 2020 Census and future censuses. The clarification in this direct final rule replaces the term ''urbanized area'' in the Phase II regulations with the phrase ''urban areas with a population of at least 50,000,'' which is the Census Bureau's longstanding definition of the term urbanized areas. This change will allow NPDES permitting authorities to use 2020 Census and future Census data in a manner that is consistent with existing longstanding regulatory practice. Because this clarification maintains the current scope of which entities are regulated as small MS4s, it is not expected to generate opposition, and EPA is publishing the clarification in the **Federal Register** as a direct final rule. As is EPA's practice for direct final rules, EPA is also publishing a parallel proposed rulemaking with the same changes included in this direct final rule if the Agency receives adverse comments.

DATES: This rule is effective on March 2, 2023 without further notice, unless EPA receives adverse comment by January 3, 2023. Comments on this rule must be received on or before January 3, 2023. If EPA receives adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2022–0834 to *https://www.regulations.gov/.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rule. 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 ''Written Comments'' heading of the Public Participation section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Huddle, Water Permits Division (MC4203), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington DC 20004; telephone number: (202) 564–7932; email address: *huddle.heather@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is publishing this rule without a prior proposed rulemaking because the Agency views this as a noncontroversial action and anticipates no adverse comment. This action is limited to clarifying that EPA will retain the existing threshold for automatic designation of small MS4s for regulation under the Phase II stormwater permitting regulations. The threshold for automatic designation was used following the 2000 and 2010 Censuses and is based on the MS4 being in an urbanized area of 50,000 or more people. This rule will maintain the

threshold for automatic designations of small MS4s and will ensure that the designation of new MS4s will continue as originally required under the Phase II regulations.

In the ''Proposed Rules'' section of the **Federal Register**, EPA is publishing a separate document that will serve as the proposed rulemaking to clarify the NPDES small MS4 urbanized area definition. If EPA receives adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. EPA would address public comments as required as part of any subsequent final rule based on the proposed rulemaking.

Table of Contents

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2022–0834, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), 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. 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.

B. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rule by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. General Information

A. Does this action apply to me?

Entities potentially regulated by this proposed action include:

Category	Examples of regulated entities	North American industry classification system (NAICS) code
Federal and state government	EPA or state NPDES stormwater permitting authorities	924110
Local governments	Operators of small municipal separate storm sewer systems	924110
State government	State departments of transportation	926120
Military	Federal military bases	928110
Public academic institutions	Publicly-administered colleges, universities, and professional schools.	611310

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table includes the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not included 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 122.28, 122.32, and 122.35, and the discussion in the preamble. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is EPA taking?

EPA is taking direct final action to clarify its NPDES Phase II regulations due to recent changes made by the Census Bureau. The changes to EPA's regulations are limited to clarifying that the designation criteria for small MS4s, which have been used since the promulgation of the regulations in 1999,

will remain the same. The clarification will be made by replacing the term previously used by the Census Bureau, ''urbanized area,'' with the phrase ''urban areas with a population of at least 50,000,'' which is the Census Bureau's longstanding criteria for defining urbanized areas.

C. What is the Agency's authority for taking this action?

The authority for this rule is the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.,* including sections 402 and 501.

D. Background

1. Statutory and Regulatory Overview

Stormwater discharges are subject to regulation under section 402(p) of the Clean Water Act (CWA). Under this provision, Congress required the following stormwater discharges initially to be subject to NPDES permitting requirements: stormwater discharges for which NPDES permits were issued prior to February 4, 1987; discharges ''associated with industrial activity;'' discharges from MS4s serving populations of 100,000 or more; and any stormwater discharge determined by EPA or a state to ''contribute . . . to a violation of a water quality standard or to be a significant contributor of pollutants to waters of the United States.'' Congress further directed EPA to study other stormwater discharges and determine which discharges needed additional controls.

EPA developed the stormwater regulations under section 402(p) of the CWA in two phases, as directed by the statute. In the first phase, under section 402(p)(4) of the CWA, EPA promulgated regulations establishing application and other NPDES permit requirements for stormwater discharges from medium (serving populations of 100,000 to 250,000) and large (serving populations of 250,000 or more) MS4s, and stormwater discharges associated with industrial activity. EPA published the final Phase I rule on November 16, 1990. 55 FR 47990. The Phase I rule, among other things, defined ''municipal separate storm sewer'' as publicly-owned conveyances or systems of conveyances that discharge to waters of the United States and are designed or used for collecting or conveying stormwater, are not combined sewers, and are not part of a publicly-owned treatment works. 40 CFR 122.26(b)(8).

In the second phase, section 402(p)(5) and (6) of the CWA required EPA to conduct a study to identify other stormwater discharges that needed further controls ''to protect water quality,'' report to Congress on the results of the study, and designate for regulation additional categories of stormwater discharges not regulated in Phase I in consultation with state and local officials. EPA promulgated the Phase II rule on December 8, 1999, designating discharges from certain small MS4s and from small construction sites (disturbing equal to or greater than one acre and less than five acres) and requiring NPDES permits for these discharges. 64 FR 68722 (December 8, 1999). A regulated small MS4 is generally defined as any MS4 that is not already covered by the Phase I program and that is located within the ''urbanized area'' boundary as determined by the latest U.S. Decennial Census. 40 CFR 122.32(a)(1) (''you are regulated if you operate a small MS4, including but not limited to systems operated by Federal, State, Tribal, and local governments, including State departments of transportation; and . . . [y]our small MS4 is located in an urbanized area as determined by the latest Decennial Census by the Bureau of the Census.'').

Separate storm sewer systems such as those serving military bases, universities, large hospitals or prison complexes, and highways are also included in the definition of ''small MS4.'' 40 CFR 122.26(b)(16). In addition, the Phase II rule includes authority for EPA (or states authorized to administer the NPDES program) to require NPDES permits for currently unregulated stormwater discharges through a designation process. 40 CFR 122.26(a)(9)(i)(C) and (D). Other small MS4s located outside of an urbanized area may be designated as a regulated small MS4 if the NPDES permitting authority determines that its discharges cause, or have the potential to cause, an adverse impact on water quality. 40 CFR 122.32(a)(2), 123.35(b)(3).

2. History of Using Urbanized Area Population Threshold for Small MS4 Designations

Since the 1950 Census, the Census Bureau has defined ''urbanized area'' as ''one or more cities of 50,000 or more and all the nearby closely settled suburban territory, or urban fringes.'' [1] This definition was in effect when EPA promulgated the Phase II Rule in 1999, and for the two censuses (2000 and 2010 Census) that have been published since then.[2] The Census Bureau's use of this population threshold is significant for the Phase II permit program because where an MS4 is located within an area identified in the latest decennial Census as having a minimum population of 50,000 or more people (*i.e.,* in an ''urbanized area''), the MS4 is automatically designated as regulated under the Phase II regulations.

The Phase II regulations have referred to the term ''urbanized area'' since the small MS4 program's inception and this term has always been used synonymously with the 50,000 population threshold. When EPA initially promulgated the Phase II regulations, EPA explained that it was adopting the Census Bureau's definition of ''urbanized area'' as one of the designation criteria for small MS4s and provided a definition of ''urbanized area'' that was identical to the Census Bureau's definition. EPA stated in the preamble to the Phase II rule that ''[u]nder the Bureau of the Census definition of 'urbanized area,' adopted by EPA for the purposes of this final rule, 'an urbanized area (UA) comprises a place and the adjacent densely settled surrounding territory that together have a minimum population of 50,000 people.'" 64 FR 68722, 68751 (December 8, 1999).

EPA acknowledged that the Census Bureau could in the future change the criteria by which it defines ''urbanized area,'' which would then in turn affect the way in which new small MS4s would be automatically designated. It is for this reason that EPA explained in the Phase II rule preamble that new MS4 designations ''will be governed by the Bureau of the Census' definition of an urbanized area in effect for that year.'' 64 FR 68722, 68751 (December 8, 1999). However, the Census Bureau has not changed the 50,000 population threshold since they adopted it 70 years ago. From the small MS4 permit program's inception in 1999, therefore, EPA and state permitting authorities have always relied on the 50,000 population threshold to automatically designate and regulate MS4s. It is only now with the 2020 Census that the Census Bureau has announced its decision to no longer separately identify ''urbanized areas.'' 87 FR 16706, 16707 (March 24, 2022).

[1] *1950 Census of Population—Preliminary Counts, Population of Urbanized Areas: April 1, 1950,* U.S. Department of Commerce, Bureau of the Census. Series PC–3 No. 9. February 1, 1951. See *https://www2.census.gov/library/publications/decennial/1950/pc-03/pc-3-09.pdf.*

[2] Urbanized areas have been defined by the Census Bureau as ''urban areas that contain 50,000 or more people . . .''. See 76 FR 53030, 53039 (August 24, 2011); and 67 FR 11663, 116667 (March 15, 2002).

III. Rationale and Summary of Direct Final Rule

A. Why a Change to the Phase II Regulations is Appropriate

This section explains how the Census Bureau's elimination of the term ''urbanized area'' relates to which MS4s are automatically designated for regulation under the Phase II regulations based on the 2020 Census and subsequent censuses.

The Census Bureau's elimination of the term ''urbanized area'' does not impact small MS4s that are already regulated under the Phase II rule. For those small MS4s already regulated because of their location in an ''urbanized area'' designated by a previous census, the Phase II regulatory history indicates that a subsequent Census Bureau change to the designation criteria for urbanized areas does not affect their regulatory status. EPA stated in the Phase II rule preamble that even if the Census Bureau were to change its ''urbanized area'' definition, ''a small MS4 that is automatically designated into the NPDES program for storm water under an urbanized area calculation for any given Census year will remain regulated regardless of the results of subsequent urbanized area calculations.'' 64 FR 68722, 68751 (December 8, 1999).[3] EPA's regulations, therefore, require continued regulation of previously designated small MS4s despite the Census Bureau's change. EPA notes that this does not prevent the operator of a qualifying MS4 so designated from requesting consideration of an NPDES waiver under 40 CFR 122.32(c).

The existing Phase II regulatory text does not explicitly instruct EPA how to treat the designation of new MS4s due to the fact that the Census Bureau's decennial censuses will no longer separately identify ''urbanized areas.'' For the 1999 Phase II rule, EPA always intended the universe of regulated small MS4s to grow in a manner commensurate with the growth of ''urbanized areas'' as identified by the latest decennial census. However, while the Phase II rule preamble explained that new MS4s would be designated in accordance with the latest census definition of ''urbanized area,'' it did not provide instruction on what to do if a decennial census no longer identifies the location of such urbanized areas. EPA is taking this action to address the Census Bureau's changes and clarify for permitting authorities and the public that it intends the scope of which small MS4s are regulated to not change, and that it will rely on what that term has always meant rather than having the regulations reference an out-of-date term.

B. Rationale for Clarification to Phase II Regulations

The most straightforward way for EPA to clarify its regulations in a manner that maintains program continuity and consistency is to replace the reference to ''urbanized area'' in the Phase II regulations with text that replicates the 50,000 population threshold on which the Census Bureau and NPDES authorities have historically relied. As discussed in Section II.D.2 of this preamble, from the inception of the small MS4 permitting program, the 50,000 population threshold has been used synonymously with the term ''urbanized area'' by both the Census Bureau and NPDES permitting authorities. Replacing the term ''urbanized area'' with text that incorporates this same 50,000 population threshold will mean that the existing method for designating small MS4s following the latest decennial census will be identical to how it has always been implemented. This change will thus ensure that there is no disruption in the designation of new MS4s and that the program is implemented in a historically consistent manner.

Substituting the obsolete references to ''urbanized areas'' with the 50,000 population threshold will also ensure that new Census 2020 mapping data and subsequent census mapping data can be used seamlessly to identify newly regulated MS4s. Prior to the recent Census Bureau changes, the location of any ''urbanized areas'' would have been automatically identified with any decennial census. Moving forward, however, each decennial census will be limited to identifying ''urban areas'' without identifying ''urbanized areas'' within those areas. Even though ''urbanized area'' locations will no longer be provided as part of the 2020 Census and future censuses, the Census Bureau will continue to provide population data for each identified urban area.[4] The availability of these population data will enable EPA and state permitting authorities to easily identify which urban areas have populations of 50,000 or more people and, therefore, to provide the necessary information to designate new MS4s.

C. Summary of Changes to Phase II Regulations

The changes to the Phase II regulations are limited to replacing the existing references to ''urbanized area'' as a criterion for designating small MS4s for regulation with text that incorporates the underlying population threshold associated with that term, or more specifically ''urban areas with a population of 50,000 or more people.'' This change is made in the following specific sections:

- 40 CFR 122.28(a)(1)(vi): This provision describes the requirement that general permits can only be used to provide coverage to discharges in a specific geographic area. The change here is to the existing list of examples of geographic or political boundary areas that meet this requirement, which currently refer to ''urbanized areas'' as one of the examples. The reference to ''urbanized areas'' here will be replaced by the described 50,000 population threshold.
- 40 CFR 122.32(a)(1): This provision currently specifies that small MS4s located in ''urbanized areas'' are regulated as small MS4s. The reference to ''urbanized areas'' here will be replaced by the described 50,000 population threshold.
- 40 CFR 122.32(d): This provision indicates that small MS4s regulated under 40 CFR 122.32(a)(1) for ''urbanized areas'' may be eligible for an NPDES waiver if they meet the applicable criteria. The reference to ''urbanized areas'' here will be substituted with a reference to the revised text in 40 CFR 122.32(a)(1).
- 40 CFR 122.33(b)(3): This provision references the ability of regulated small MS4s located in the same ''urbanized area'' as a medium or large MS4 to be

[3] EPA's statement in its entirety: ''Based on historical trends, EPA expects that any area determined by the Bureau of the Census to be included within an urbanized area as of the 1990 Census will not later be excluded from the urbanized area as of the 2000 Census. However, it is important to note that even if this situation were to occur, for example, due to a possible change in the Bureau of the Census' urbanized area definition, a small MS4 that is automatically designated into the NPDES program for storm water under an urbanized area calculation for any given Census year will remain regulated regardless of the results of subsequent urbanized area calculations.''

[4] In its *2020 Urban Areas Frequent Asked Questions,* the Census Bureau provided the following answer in response to the question ''Is it true that the Census Bureau is no longer defining urbanized areas?'': ''No. The Census Bureau will no longer identify an individual urban area as either an urbanized area or an urban cluster. We will refer to all areas as ''urban areas'' regardless of population size. *We will publish population and housing counts for each urban area when we announce results of the 2020 Census urban area delineation. Data users and program will be able to use those counts and subsequent American Community Survey estimates to categorize urban areas according to population size.*'' (emphasis added) See *https://www2.census.gov/geo/pdfs/reference/ua/2020_Urban_Areas_FAQs.pdf.*

included as a limited co-permittee in the same NPDES permit as the medium or large MS4. The reference to ''urbanized area'' will be modified to read ''urban area'' instead.

• 40 CFR 123.35(b)(1)(ii): This provision includes a reference to an ''urbanized area'' in the context of regulatory guidance on criteria that state permitting authorities may use to designate other small MS4s for regulation, including ''contiguity to an urbanized area.'' The reference to ''urbanized area'' will be replaced by the described 50,000 population threshold.

• 40 CFR 123.35(b)(2): This provision includes a reference to an ''urbanized area'' in the context of applying state permitting authority criteria for designating additional small MS4s for regulation, including MS4s located outside of an ''urbanized area'' serving a jurisdiction with a population density of at least 1,000 people per square mile and a population of at least 10,000. The reference to ''urbanized area'' will be replaced by the described 50,000 population threshold.

• 40 CFR 123.35(d)(1): This provision indicates that small MS4s regulated under 40 CFR 122.32(a)(1) for ''urbanized areas'' may be eligible for an NPDES waiver if they meet the applicable criteria. The reference to ''urbanized areas'' here will be substituted with the described 50,000 population threshold.

D. Costs of This Action

The regulatory clarifications in this rule ensure that the population basis for regulating small MS4s will remain the same. As a result, these clarifications will not result in increased costs to small MS4 permittees or to state and EPA permitting programs, nor will it regulate additional MS4s beyond what was required by the 1999 Phase II regulations.

E. Direct Final Rule Implementation and Technical Assistance

The changes made by this direct final rule will become effective on March 2, 2023, assuming no adverse comments are received. Because this rule effectively retains the population basis used since the promulgation of the Phase II regulations to designate new small MS4s following a decennial census, EPA expects permitting authorities to be able to implement the revisions in the rule immediately.

EPA plans to continue to provide technical assistance to permitting authorities in a number of different ways to help with the implementation of the MS4 program following publication of the new census data. The following is a summary of EPA's planned technical assistance activities:

• *Publish new MS4 mapping information:* Following the publication of the 2020 Census urban area information, EPA will be able to determine which urban areas have a population of 50,000 or more people and thereby identify which areas meet the revised rule's criteria for small MS4s. EPA plans to use the 2020 Census data to publish mapping information that will show where urban areas with a population of 50,000 or more people are located in the United States and where these areas are located with respect to municipal boundaries. This information will enable permitting authorities to determine which jurisdictions are likely operating MS4s within urban areas that meet the 50,000 population threshold. EPA also plans to provide mapping information that compares the 2010 Census and 2020 Census location of these urban areas. Permitting authorities will be able to use this information to pinpoint the location of new MS4s and compare how the urban area boundaries have changed since the 2010 Census for existing MS4s.

• *Provide permitting authorities with a draft list of new MS4s:* To assist NPDES permitting authorities, EPA plans to use the mapping information described under the previous bullet point to preliminarily identify new MS4s that are located within the urban areas meeting the population threshold. EPA provided a similar list of new MS4s following the 2010 Census. Permitting authorities are then free to evaluate the MS4s identified on this list to determine if they are accurate and whether any changes are needed.

• *Provide guidance materials:* EPA will provide additional guidance related to the process of permitting newly designated MS4s that NPDES authorities may choose to use. EPA provided similar guidance following the publication of the 2010 Census, which included tips on the suggested steps to follow from initial contact with the new MS4 operators to including them in the applicable NPDES permit. EPA also provided a letter template that permitting authorities could use to inform new MS4 operators of their designation and what to expect from the permitting process moving forward. The Agency plans to update these materials for the 2020 Census, and to explore what additional technical assistance may be needed. EPA will engage with its Federal and state permitting authority partners to determine which type of assistance may be the most beneficial.

• *Rescind interim guidance:* Earlier this year, EPA published on its website *Interim Guidance on Census Elimination of ''Urbanized Areas''* (see *https://www.epa.gov/npdes/interim-guidance-census-elimination-urbanized-area-definition*). The guidance was intended to provide interim recommendations to permitting authorities regarding the implementation of their small MS4 permitting programs following the finalization of the Census Bureau's designation criteria changes while EPA evaluated how best to clarify its regulations. Assuming this rule becomes effective on March 2, 2023, the interim guidance will no longer be necessary. Upon the effective date of this rule, EPA will rescind the interim guidance.

VI. Statutory and Executive Orders Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2040–0004. This rule contains no new requirements for reporting and recordkeeping.

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. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule has no net burden on the small entities subject to the rule. EPA is limiting its changes to substituting use of the term ''urbanized area'' in the four subsections of the Phase II regulations with the underlying population criteria that has been used synonymously with this term since the 1999 promulgation of the regulations.

See discussion in Sections III.B and C of this preamble. Although making this clarification is important to ensure program continuity and consistency, EPA views this change as akin to a clerical correction to remove an obsolete term and ensure that program applicability remains unchanged. The Agency has therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments, or the private sector.

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 does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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

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

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rule does not involve technical standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

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 people of color, low-income populations, and/or indigenous peoples. This action makes a technical clarification to a previously promulgated regulatory action, and will not change the human health and environmental conditions that currently exist with the implementation of the Phase II regulations.

The EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This regulatory action is a technical clarification to a previously promulgated regulatory action and does not have any disproportionate and adverse impact on people of color, low-income populations and/or indigenous peoples.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 122

Environmental protection, Stormwater, Water pollution.

40 CFR Part 123

Environmental protection, Stormwater, Water pollution.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, EPA amends 40 CFR parts 122 and 123 as set forth below:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 2. Amend § 122.28 by revising paragraph (a)(1)(vi) to read as follows:

§ 122.28 General permits (applicable to State NPDES programs, see § 123.25).

(a) * * *

(1) * * *

(vi) Urban areas with a population of 50,000 or more people as determined by the latest Decennial Census by the Bureau of the Census; or

* * * * *

■ 3. Amend § 122.32 by revising paragraph (a)(1) and paragraph (d) introductory text to read as follows:

§ 122.32 As an operator of a small MS4, am I regulated under the NPDES storm water program?

(a) * * *

(1) Your small MS4 is located in an urban area with a population of 50,000 or more people as determined by the latest Decennial Census by the Bureau of the Census. (If your small MS4 is not located entirely within an urban area with a population of 50,000 or more people, only the portion that is within this urban area is regulated); or

* * * * *

(d) The NPDES permitting authority may waive permit coverage if your MS4 serves a population of less than 1,000 within the urban area identified in paragraph (a)(1) of this section and you meet the following criteria:

* * * * *

■ 4. Amend § 122.33 by revising paragraph (b)(3) to read as follows:

§ 122.33 Requirements for obtaining permit coverage for regulated small MS4s.

* * * * *

(b) * * *

(3) *Co-permittee alternative.* If the regulated small MS4 is in the same urban area as a medium or large MS4 with an NPDES storm water permit and that other MS4 is willing to have the small MS4 operator participate in its storm water program, the parties may jointly seek a modification of the other MS4 permit to include the small MS4 operator as a limited co-permittee. As a limited co-permittee, the small MS4 operator will be responsible for compliance with the permit's conditions applicable to its jurisdiction. If the small MS4 operator chooses this option it must comply with the permit application requirements of § 122.26, rather than the requirements of § 122.33(b)(2)(i). The small MS4 operator does not need to comply with the specific application requirements of § 122.26(d)(1)(iii) and (iv) and (d)(2)(iii) (discharge characterization). The small MS4 operator may satisfy the requirements in § 122.26 (d)(1)(v) and (d)(2)(iv) (identification of a management program) by referring to the other MS4's storm water management program.

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

■ 5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 6. Amend § 123.35 by revising paragraph (b)(1)(ii), (b)(2), and (d)(1) introductory text to read as follows:

§ 123.35 As the NPDES Permitting Authority for regulated small MS4s, what is my role?

* * * * *

(b) * * *

(1) * * *

(ii) Guidance: For determining other significant water quality impacts, EPA recommends a balanced consideration of the following designation criteria on a watershed or other local basis: discharge to sensitive waters, high growth or growth potential, high population density, contiguity to an urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census, significant contributor of pollutants to waters of the United States, and ineffective protection of water quality by other programs;

(2) Apply such criteria, at a minimum, to any small MS4 located outside of an urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census serving a jurisdiction with a population density of at least 1,000 people per square mile and a population of at least 10,000;

* * * * *

(d) * * *

(1) You may waive permit coverage for each small MS4s in jurisdictions with a population under 1,000 within the urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census where all the following criteria have been met:

* * * * *

[FR Doc. 2022–26228 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2021–0015; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BB27

Endangered and Threatened Wildlife and Plants; Lesser Prairie-Chicken; Threatened Status With Section 4(d) Rule for the Northern Distinct Population Segment and Endangered Status for the Southern Distinct Population Segment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

Correction

In the rule document 2022–25214 beginning on page 72674 of the issue of Friday, November 25, 2022, make the following correction:

§ 17.41 [Corrected]

■ On page 72754, following Figure 1 to paragraph (k), in the first column, add the following paragraph:

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Northern DPS of the lesser prairie-chicken. Except as provided under paragraph (k)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

[FR Doc. C1–2022–25214 Filed 12–1–22; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2022–0024; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BG21

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Dixie Valley Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, are listing the Dixie Valley toad (*Anaxyrus williamsi*), a toad species from Nevada, as an endangered species under the Endangered Species Act of 1973, as amended (Act). This rule continues the protections of the Act applied to the Dixie Valley toad under our April 7, 2022, temporary emergency listing rule.

DATES: This rule is effective December 2, 2022.

ADDRESSES: This final rule and supporting documents are available on the internet at *https://www.regulations.gov* in Docket No. FWS–R8–ES–2022–0024.

FOR FURTHER INFORMATION CONTACT: Justin Barrett, Field Supervisor, U.S. Fish and Wildlife Service, Reno Fish and Wildlife Office, 1340 Financial Blvd., Suite 234, Reno, NV 89502; telephone 775–861–6300. 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:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that the Dixie Valley toad meets the

definition of an endangered species; therefore, we are listing it as such. Listing a species as an endangered or threatened species can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process.

What this document does. This rule makes final the listing of the Dixie Valley toad as an endangered species.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the Dixie Valley toad is at risk of extinction throughout its range primarily due to the threat of geothermal development and its effects to the toad and the habitat on which it depends. Other threats to the Dixie Valley toad include climate change; chytrid fungus; groundwater pumping associated with human consumption, agriculture, and county planning; and predation by invasive bullfrogs. In addition, existing regulatory mechanisms may be inadequate to protect the species.

List of Acronyms

We use many acronyms in this rule. For the convenience of the reader, we define some of them here:

afy = acre-feet per year
January Environmental Assessment (EA) = January 2021 Draft EA (Bureau of Land Management (BLM) 2021a, entire)
January Monitoring and Mitigation Plan = January 2021 Aquatic Resources Monitoring and Mitigation Plan (BLM 2021a, Appendix H)
November Environmental Assessment (EA) = November 2021 Final EA (BLM 2021b, entire)
November Monitoring and Mitigation Plan = November 2021 Aquatic Resources Monitoring and Mitigation Plan (BLM 2021b, Appendix H)
BLM = Bureau of Land Management
°C = degrees Celsius
CBD = Center for Biological Diversity
CFR = Code of Federal Regulations
cfs = cubic feet per second
m3/yr = cubic meters per year
DoD = Department of Defense
Act = Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*)
EA = environmental assessment
°F = degrees Fahrenheit
NAS Fallon = Fallon Naval Air Station
FR = Federal Register
ft = feet
gpm = gallons per minute
in = inch
km = kilometer
MW = megawatt
m = meter
mm = millimeter
NAC = Nevada Administrative Code
NDOW = Nevada Department of Wildlife
NDNH = Nevada Division of Natural Heritage
NDWR = Nevada Division of Water Resources
Fallon Paiute Shoshone Tribe = Paiute-Shoshone Tribe of the Fallon Reservation and Colony
RCP = representative concentration pathway
SSA = species status assessment
Service = U.S. Fish and Wildlife Service
USGS = U.S. Geological Survey

Previous Federal Actions

We received a petition from the Center for Biological Diversity (CBD) on September 18, 2017, requesting that the Dixie Valley toad be listed as an endangered or threatened species and that the petition be considered on an emergency basis (CBD 2017, entire). The Act does not provide a process to petition for emergency listing; therefore, we evaluated the petition to determine if it presented substantial scientific or commercial information indicating that the petitioned action may be warranted. We published a 90-day finding in the **Federal Register** on June 27, 2018 (83 FR 30091), stating that the petition presented substantial scientific or commercial information indicating that listing the Dixie Valley toad may be warranted.

On April 7, 2022, we published an emergency rule (87 FR 20336) that applies Federal protection under the Act to the Dixie Valley toad for a 240-day period, ending on December 2, 2022. On April 7, 2022, we concurrently published a proposed rule (87 FR 20374) to list the Dixie Valley toad as an endangered species under the Act, and we requested public comments on that proposal for 60 days, ending June 6, 2022.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Dixie Valley toad. The SSA team was composed of Service biologists, in consultation with other scientific experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought peer review of the SSA report. The Service sent the SSA report to four independent peer reviewers and received three responses. The purpose of peer review is to ensure that our listing determinations are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the biology, habitat, and threats to the species. The Service also sent the SSA report to three partner agencies, BLM, NDOW, and DoD, and we received comments from BLM and NDOW. Comments we received during peer and partner review were considered and incorporated into our SSA report and this final listing rule.

Summary of Changes From the Proposed Rule

Based upon our review of the public comments, State agency comments, peer and partner review comments, and relevant information that became available since the proposed rule published (87 FR 20374; April 7, 2022), we updated information in our SSA report, including:

- Adding additional individual toad locations provided by NDOW.
- Revising the SSA report to include the Dixie Valley toad as a protected species in the State of Nevada.
- Adding information from a newly published scientific paper (Rose et al. 2022, entire) regarding occupancy dynamics of the Dixie Valley toad and the different environmental conditions adult and larval toads require.
- Clarifying the changes from the BLM's January draft environmental assessment (EA) to the BLM's November final EA.
- Clarifying how the Dixie Valley toad uses colder springs in the wetlands.
- Adding the Traditional Ecological Knowledge provided by the Fallon Paiute Shoshone Tribe to section 1.2 of the SSA report.
- Adding information on the differences between Dixie Meadows and the McGinness Hills, Tungsten Mountain, and Ngatamariki sites.

We also made changes as appropriate in this final rule. In addition to minor clarifying edits and the incorporation of additional information on the species' biology, populations, and threats, this final rule differs from the proposed rule by clarifying why the changes made between the BLM's January draft EA and the BLM's November final EA did not change our conclusion that the Dixie Valley toad meets the Act's definition of an endangered species.

Summary of Comments and Recommendations

Peer Reviewer Comments

As discussed in Supporting Documents, above, we received comments from three peer reviewers. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the information contained in the SSA report. The peer reviewers generally concurred with our methods and conclusions, and they provided support for thorough and descriptive narratives of assessed issues, as well as additional information, clarifications, and suggestions to improve the final SSA report. Peer reviewer comments are addressed in the following summary and were incorporated into the final SSA report as appropriate.

(1) *Comment:* One peer reviewer stated that chytrid-positive bullfrogs do not occur in the southern part of the Dixie Valley toad's range. Rather, there is a potential path for introduction of chytrid fungus into Dixie Valley toads from chytrid-fungus-positive American bullfrogs already occurring in Turley Pond, located about 10 kilometers (about 5.7 miles) from Dixie Meadows, to bullfrogs co-occurring with Dixie Valley toads in the southern part of the range.

Our Response: We have clarified that the location of the chytrid-fungus-positive bullfrogs in Dixie Valley is in Turley Pond, approximately 10 kilometers from Dixie Meadows.

(2) *Comment:* One peer reviewer asked if the effects of all other uses of groundwater and extended drought would be negligible compared to the impacts of the geothermal development.

Our Response: Because the geothermal project constitutes the most significant potential localized water-related impact to the springs/wetland complex providing habitat for the Dixie Valley toad, any localized effects of groundwater withdrawals within Dixie Valley, like changes in local climatic conditions, are potential secondary interacting effects.

(3) *Comment:* One peer reviewer suggested we add historical baselines to the species needs table to better understand how changes in flow and water temperature would affect the species.

Our Response: There is little or no information on historical baselines for springflow and water temperature. We used the best available scientific and commercial data from recent studies to determine what the Dixie Valley toad's resource needs are, which are discussed in section 3.3 of the SSA report.

Comments From Tribes

We received comments from the Pauite-Shoshone Tribe of the Fallon Reservation and Colony, Nevada (hereafter Fallon Paiute Shoshone Tribe), expressing support for the listing of the Dixie Valley toad. The Fallon Paiute Shoshone Tribe discussed how Dixie Valley is ancestral territory where they have lived and prayed for more than 10,000 years and is one of the most sacred sites in the Tribe's culture. The Fallon Paiute Shoshone Tribe's reverence for the site includes the ecosystem it supports; thus, they strongly endorse listing the Dixie Valley toad as endangered.

(4) *Comment:* One Tribal commenter requested that we consider and integrate the Fallon Paiute Shoshone Tribe interests into the final rule. The Tribal commenter provided numerous reasons documenting why the Dixie Meadows ecosystem (also known as Paumu, and including the surface waters of the springs, the surrounding wetlands, the surrounding uplands, and the endemic toad) is of cultural and spiritual significance, such as use of the area for cultural and spiritual practices, and the need to safeguard and properly manage the interests of Indian Tribes. Further, the Tribe asserted that if the springs cease flowing, it would be devastating to both the Dixie Valley toad and the Tribe.

Our Response: We have updated the SSA report to include the Traditional Ecological Knowledge provided by the Fallon Paiute Shoshone Tribe in section 1.2.

(5) *Comment:* One Tribal commenter asserted that the entire proposed project must be halted until such time as the BLM consults with the Service under section 7 of the Act and highlighted the importance of halting construction activities and immediately consulting based on Tribal observations of activities detrimental to the Tribe (*e.g.,* construction within approximately 500 feet of surface waters, construction runoff toward the springs, trash in and around the springs, a port-a-potty flowing into the ground, and multiple disturbances) and to the Dixie Valley toad (*i.e.,* the risk of crushing or harming toads). The Tribe requested government-to-government consultation with the Service at its earliest convenience and prior to a final determination on the proposed rule.

Our Response: We are working toward initiating conversations with the Fallon Paiute Shoshone Tribe. BLM began informal consultation with us on April 7, 2022.

Comments From State Agencies

(6) *Comment:* One commenter recommended we get clarification or verification that chytrid-fungus-positive results have been limited to Turley Pond, which is within Dixie Valley but not within the Dixie Valley toad's known range. They stated that recent work evaluating past and current chytrid-fungus sampling data to develop monitoring-protocol recommendations (including sampling in Dixie Meadows and surrounding ponds) is being prepared for journal submission. The commenter recommended contacting the authors to incorporate the most up-to-date information.

Our Response: We have clarified the location of the chytrid-fungus-positive American bullfrogs, as discussed above under our response to (1) *Comment.* The paper referred by the commenter is in review at the Journal of Wildlife Diseases; however, the associated data release from USGS was used in the SSA report and cited as Kleeman et al. (2021, entire).

(7) *Comment:* One commenter recommended we include a discussion on invasive plants, like Russian olive (*Elaeagnus angustifolia*) and tamarisk (*Tamarix* spp.), as contributing factors in the cumulative analysis, as these species are present within the Dixie Valley toad's range.

Our Response: Section 3.3.3 in the SSA report acknowledges the presence of certain invasive plant species within Dixie Meadows. We do not have information regarding any population-level threat from these invasive plant species.

Public Comments

We received thousands of comments asserting various opinions, including that human-induced threats of geothermal development and climate are extensive and irreparably damaging for the Dixie Valley ecosystem and pose a threat to the Dixie Valley toad; suggesting that alternative sites or type of renewable energy source would be better suited to ensure the viability of the Dixie Valley toad; that the developer of the geothermal power plant should be denied a permit because of the environmental damage it will cause to the Dixie Valley toad and its habitat; and that an adequate monitoring plan should be developed and implemented for the Dixie Valley toad. The public comments overwhelmingly urged us to list the toad as an endangered species under the Act. Some of these comments were outside of the scope of this final determination; below, we respond to

substantive comments regarding the listing determination.

(8) *Comment:* One commenter asserted that the proposed rule to list the Dixie Valley toad as an endangered species would significantly adversely affect the social and economic future of Churchill County.

Our Response: In making a determination as to whether a species meets the Act's definition of an endangered or threatened species, under section 4(b)(1)(A) of the Act the Secretary is to make that determination based solely on the basis of the best scientific and commercial data. Therefore, we did not evaluate the social and economic impacts of listing the Dixie Valley toad or consider such impacts in this final determination. Under the Act, the Service may evaluate economic impacts only in association with the designation of critical habitat under section 4(b)(2); the Service has concluded that the designation of critical habitat for the Dixie Valley toad is not determinable at this time and, therefore, is not designating critical habitat as part of this rulemaking.

(9) *Comment:* One commenter claimed that the analysis of threats was incomplete, misrepresented, and did not include all applicable science and information. The commenter stated that it is contradictory to say that the Dixie Valley toad is thriving while concurrently reporting that there is a lack of known water-quality parameters that is preferred by the toad.

Our Response: While we still have much to learn about Dixie Valley toads, all monitoring to date indicates that all age classes of the toad are present in Dixie Meadows and breeding is occurring annually. Water-quality parameters are not known with great detail, as described in section 3.3.4 of the SSA report; however, we used the best scientific and commercial data available to inform this rule.

(10) *Comment:* One commenter stated we should have done an analysis on historical wetted area of the wetlands using aerial photography from 1954 to present, Landsat imagery from 1984–2012, and National Agriculture Inventory Program images.

Our Response: The Service used a Desert Research Institute report that analyzed much of the information the commenter is suggesting. This information can be found in section 4.2.10 in the SSA report and the corresponding report (Albano et al. 2021, entire).

(11) *Comment:* One commenter claims our statement that urban development, agriculture, and energy production facilities will likely place additional demands on already limited water resources is not an accurate depiction of activities occurring in Dixie Valley because there is limited private land where these activities may occur. The commenter stated that the private land that existed in Dixie Valley during the 1990s was acquired by the Fallon Naval Air Station, thus limiting these activities in Dixie Valley.

In addition, the commenter stated that we did not incorporate the pending DoD/Navy land withdrawals from the Dixie Valley Training Area, which would include the entire valley bottom from the south side of Dixie Meadows to State Highway 50. The commenter stated that this further shows why urban development and agriculture are unlikely to occur in Dixie Valley. Additionally, the commenter stated that we should have included a map of land ownership in Dixie Valley.

Our Response: Our statement regarding an increase in urban development, agriculture, and energy production facilities was in the context of the entire Southwest. Both human settlements and natural ecosystems in the southwestern United States are largely dependent on groundwater resources, and decreased groundwater recharge may occur as a result of climate change (U.S. Global Change Research Program 2009, p. 133). Furthermore, the human population in the Southwest is expected to increase 70 percent by mid-century (Garfin, 2014, p. 470). Resulting increases in urban development, agriculture, and energy production facilities will likely place additional demands on already limited water resources. Climate change will likely increase water demand while at the same time shrink water supply, as water loss may increase evapotranspiration rates and run-off during storm events (Archer and Predick 2008, p. 25). Overall, demand for water is likely to go up and available water resources will likely decrease.

An example of increased local water demand is the Dixie Valley Water Project, which is being proposed to provide more water to the neighboring valley experiencing increased urbanization and agriculture growth. There is no information on where water will be withdrawn for the Dixie Valley Water Project; however, we know that the basin is overallocated (NDWR 2021, entire), which could plausibly affect the amount of water in Dixie Meadows. According to the NDWR, two water right applications are pending in Dixie Meadows, seeking water for municipal use, which indicates that there could be increased water demand in Churchill County. Although urban development and agriculture may not increase within Dixie Valley, increases in urbanization and agriculture in surrounding areas may have an impact on water resources in Dixie Valley.

(12) *Comment:* One commenter stated that we used out-of-date information regarding estimates of perennial yield in Dixie Valley. They claimed that our estimate of 15,000 acre-feet per year (from an abstract on the NDWR website) has been updated on the order of 23,000 acre-feet per year, pointing out three studies (Garcia et al. 2015, entire; Huntington et al. 2014, entire; Smith et al. 2016, entire) that were not cited in the proposed rule and that the commenter believes should have been incorporated into the expert elicitation panel considerations.

Our Response: We used the best scientific and commercial data available, which in this case is the NDWR (NDWR 2021, entire). We could not find mention of perennial yield in Huntington et al. (2014, entire); however, the author of this scientific paper was one of the expert panelists, and, therefore, this information was considered during the expert elicitation. We also could not find mention of perennial yield in Garcia et al. (2015, entire). Garcia et al. (2015, pp. 1, 75, 78, 80) found an estimate of groundwater discharge by evapotranspiration to be 23,000 acre-feet, but evapotranspiration does not equal perennial yield. Smith et al. (2016, pp. 1, 28, 175) gives a potential perennial yield of the combined Dixie-Fairview-Jersey Valley system of 23,000 acre-feet per year; however, the 15,000 acre-feet per year we cite is from Dixie Valley only. After reviewing the studies referenced in this comment, we continue to conclude that the NDWR has the best available data because it is the authority on water resources in Nevada.

(13) *Comment:* One commenter stated that we analyzed and reported appropriated water rights in the Dixie Valley as part of our analysis, and that we should have reported estimates of actual consumptive use, which the commenter stated has decreased since the 1980s.

Our Response: We used appropriated water rights in the Dixie Valley because that is the amount of water that could plausibly be used. Because appropriated water is authorized for use and readily available, we considered the possibility that it could be used in the future. No estimates of consumptive use were provided by the commenter and the NDWR does not compile pumping inventories for Dixie Valley.

(14) *Comment:* One commenter stated that we included broad statements about

the Dixie Valley basin being fully appropriated for consumptive groundwater uses in both the emergency listing rule (87 FR 20336; April 7, 2022) and the SSA report, and that these types of broad statements of the status of a basin as large as Dixie Valley can be misguided and misleading. The commenter also asserted that water quality in Dixie Meadows is very poor for human consumption and there is no interest from the County in accessing waters associated with Dixie Meadows.

Our Response: We were unable to find information on where water will be withdrawn from the Dixie Valley Water Project; however, we know that the basin is overallocated (NDWR 2021, entire), which could plausibly affect the amount of water in Dixie Meadows. According to the NDWR, Churchill County has two water right applications in review (6 cubic feet per second each) in Dixie Meadows for municipal use. Citations supporting the assertion that water quality in Dixie Meadows is poor for human consumption were not provided. Because the Dixie Valley Basin is overallocated and two applications for water rights for municipal use are held by the County within Dixie Meadows, we considered the potential effects of consumptive groundwater use on the Dixie Valley toad.

(15) *Comment:* One commenter claimed that Churchill County could develop the Dixie Valley Water project in a manner that has minimal impact on the Dixie Meadows groundwater resources based on monitoring and modeling work completed by the County.

Our Response: The commenter did not provide data or information on monitoring and modeling work done by the County, and we did not find any publicly available information that would allow us to take this information into consideration in this final rule. We cannot incorporate conservation efforts into our analysis that have not been confirmed or proven, in accordance with our Policy for Evaluation of Conservation Efforts When Making Listing Decisions (68 FR 15100; March 28, 2003).

(16) *Comment:* One commenter disagreed with our statement that Dixie Meadows has evolved with little historical variation, claiming our statement is not proven or established. The commenter stated that we should have analyzed past land use of Dixie Meadows to demonstrate previous uses that may have significantly altered habitat. They stated that there is a high probability that the meadow was homesteaded, farmed, or altered by early settlers and Native Americans.

Our Response: Section 4.2.10 of the SSA report discusses evidence of spring modifications and their potential impacts to the Dixie Valley toad and its habitat. Historical water management of Dixie Meadows has likely had negative impacts on how water flows through the wetlands as evidence of dikes, channelization, and deteriorating pipes can be found throughout the area (Stantec 2019, pp. 13, 50–51, 104–105, 132–133; Albano et al. 2021, pp. 72–75). However, the needs of the species have not changed due to this historical alteration.

(17) *Comment:* One commenter stated that we did not take an active role in the development of the Aquatic Resources Monitoring and Mitigation Plan (hereafter referred to as the Monitoring and Mitigation Plan), and the experts participating in our expert elicitation panel should have had the opportunity to interface with the Monitoring and Mitigation Committee. The commenter also stated that had the Service coordinated with Ormat (as well as with other pertinent agencies) to improve the Monitoring and Mitigation Plan, then emergency listing the Dixie Valley toad would have not been necessary.

Our Response: Sections 4.2.2 and 4.2.3 of the SSA report summarize coordinated efforts between the BLM and the Service on the geothermal plant and associated Monitoring and Mitigation Plan, including the detailed comments that the Service provided on the January draft EA and Monitoring and Mitigation Plan on February 12, 2021.

(18) *Comment:* One commenter stated that the primary basis for our listing decision was based on the expert panel's predictions on the impacts of the Dixie Meadows Project.

Our Response: The SSA report contains our full analysis of all the factors that could affect the continued existence of the Dixie Valley toad. Because the Dixie Meadows project is a key factor that could affect the species' viability, the expert panel was assembled to help characterize the uncertainty around its potential impacts. The panel was composed of expert groundwater hydrologists, hydrogeologists, and geologists, including one of the foremost experts on geothermal systems in Nevada, and their judgments provide a reasonable basis for assessing the risk from geothermal development.

While the risk of changes to the species' habitat from geothermal development is one aspect of the assessment and the primary threat to the species, the Dixie Valley toad's narrow range, limited opportunities for dispersal, risk of exposure to chytrid fungus, and projected changes in climate, among other factors, were also considered in the listing decision.

(19) *Comment:* We received multiple comments on the materials provided to the expert panelists for the expert elicitation. Commenters stated that the materials provided were inadequate to provide the experts with understanding of the Dixie Meadows geothermal project, investigations conducted at the site, the hydrogeology of the overall area, or the threats to the toad.

Our Response: The materials provided to the panelists served a specific purpose as part of accepted best practices for structured expert knowledge elicitation and is only one component of the elicitation process (Gosling 2018, entire; O'Hagan 2019, pp. 73–81; Oakley and O'Hagan 2019, entire). The expert panelists had access to the best available information at the time of the assessment, including the January EA, January 2021 Monitoring and Mitigation Plan for the Dixie Meadows project, all publicly available related materials, and published scientific reports and papers. The expert panelists also have significant professional experience in hydrogeology and the Dixie Valley region and were provided an opportunity to identify any additional studies relevant to the expert knowledge elicitation based on their own professional experience in hydrogeology and the Dixie Valley region. The information provided is based on credible, published scientific sources and is not designed to be an exhaustive reference.

(20) *Comment:* One commenter stated that that the materials provided to the expert panel that described the location of the major piedmont fault at Dixie Meadows as being coincident with the thermal springs, and additionally that the same fault is the main producing structure at the Comstock and Dixie Valley Power Plant geothermal sites, was a ''gross over-simplification.'' This led the expert panelists to make ill-informed interpretations about the dynamics of fluid flow at Dixie Meadows in relation to characteristics of the springflows, and consequently toad habitat, and compromised the ability of the panelists to make informed decisions based on the ''best available science.'' The commenter also stated that the above is clearly incorrect since it would also mean that all three geothermal systems/cells are connected, which the commenter stated is known not to be the case.

Our Response: Geologic and geophysical investigations conducted beginning in the 1960s have been interpreted to show that the trace of the piedmont fault passes through Dixie Meadows at a location that is nearly coincident (just west) of the thermal springs, and that portions (sections) of the same piedmont fault, which runs up the west side of the valley, are the primary producing structures at the Comstock and Dixie Valley Power Plant geothermal sites, respectively; the commenter incorrectly interprets this evidence as necessitating that the three geothermal cells are hydraulically connected along the length of the piedmont fault (AltaRock Energy Inc. 2014ab, entire).

(21) *Comment:* One commenter stated that the materials provided to the expert panel omitted information describing that dilation zones (*e.g.,* at the intersections of faults striking in different directions) are determinant of the locations of identifiable, separate geothermal cells in Dixie Valley. The commenter stated that each dilation zone is ''unique.'' The commenter also stated that this led the expert panelists to make ill-informed interpretations about the dynamics of fluid flow at Dixie Meadows in relation to characteristics of the springflows providing habitat for the Dixie Valley toad.

Our Response: The role of dilation zones as determinant of the occurrence of geothermal cells, which are hydraulically separate, on the west side of Dixie Valley is published in a major Department of Energy-funded study that was available to the expert panelists (AltaRock Energy Inc. 2014a, part I). Thus, this information was considered in our determination.

(22) *Comment:* One commenter expressed concern that the January 11, 2021, version of the Monitoring and Management Plan was used by the expert elicitation panel conducted by the Service in August 2021, noting that ''significant changes'' were made in the final version of the plan that was published on November 22, 2021. Two commenters stated that the changes to the plan and project have specific relevance to items of concern identified by us and the expert panelists and described in the proposed and emergency listing rules (87 FR 20374 and 87 FR 20336, both published on April 7, 2022). Specifically, the commenters noted the following changes/additions: (a) implementing a phased power plant development approach; (b) improving data and interpretations regarding the project's flow system and hydrogeologic characterization, including enhanced characterization of the long-recognized basin-fill hydrothermal plume and an enhanced description of the 2017 ''flow test'' performed using wells proposed for use in Phase 1 of the project; and (c) modifying and clarifying the period of baseline data collection, clarifying what parameters would be monitored, increasing the frequencies of water quality monitoring and other field measurements, installing additional monitoring wells in the basin-fill hydrothermal plume west of the springs, and/or suspending power generation operations should conservation measures be ''non-satisfactory'' in maintaining the aquatic habitat at Dixie Meadows.

The commenter(s) stated that the Service did not acknowledge the phased power plant development approach and did not analyze or disclose how this assumption affected the expert panelists' projections of the project's impacts; the new information provided rendered the expert panelists' opinions regarding risk(s) posed to the springs/wetlands complex supporting the toad marginally relevant, at best; and/or changes made between the January Monitoring and Mitigation Plan reviewed by the expert panelists and the final version were not minimal, disagreeing with our conclusion that changes and additions made to the November Monitoring and Mitigation Plan were ''minimal'' and did not affect the ability of the plan ''to detect or mitigate changes'' (*i.e.,* to provide a robust set of protections).

Our Response: The SSA considered the possibility of a phased approach to development. The expert panelists considered the power plant may be managed adaptively (Service 2022, appendix A) when thinking about the timeframe of system changes. This information is captured in the estimates of uncertainty for the various judgments. Even if development is phased, the total production amount approved remains a relevant quantity for assessing risk. Expert judgments on timeframes were based on the point at which the power plant begins operating (Service 2022, appendix A). Moreover, the phased power plant development approach results in no significant improvement to the efficacy or reliability of the November Monitoring and Mitigation Plan or reduction in the potential for adverse project impacts to the springs/wetlands (ability to detect or mitigate project-induced changes) given that the overall magnitude, number, and specific locations of geothermal fluid extraction and injection for each operational phase (12- versus 60–MW) will differ greatly. Additionally, the Service, in evaluating the threat of geothermal development under Factor A (the present or threatened destruction, modification, or curtailment of the species' habitat or range) in making a final listing decision, fully considered the phased approach described in BLM's Decision Record, November final EA, and November Monitoring and Mitigation Plan.

The 2017 ''flow test,'' that is the only field-scale, multi-well pumping or injection test performed at the site to date, is of limited informational value because test pumping and injection were performed simultaneously at comparable rates in relatively close proximity over a limited period of time (compared to the proposed 1-year 12–MW operation), the test included no bedrock monitoring wells between the area of proposed project operations and the springs, depth of water in spring pools was monitored rather than more precise/sensitive springflows, and efforts to interpret the fate of injected tracers were largely unsuccessful.

Further, changes and additions made in the November Monitoring and Mitigation Plan resulted in minimal, if any, improvement in the hydrogeologic characterization of the site, refinement of the proposed hydrogeologic conceptual model, increase in the capacity of the monitoring plan to provide effective warning of the propagation of project impacts to the springs and habitat for the toad, or mitigation of any such impacts. Although the BLM's Decision Record discusses suspension of operations, there is a lack of detail in the November Monitoring and Mitigation Plan about a definite schedule for recurring review of monitoring results, the timeline for adaptive management refinements to occur, and length of time between data collection, lab results getting generated, reviewed, and interpreted, and time until a decision is made and implemented about if/when/how to mitigate any adverse effects.

(23) *Comment:* Two commenters stated that the monitoring established in the November Monitoring and Mitigation Plan will ensure early detection of any changes in the geothermal system prior to the effects spreading to the springs, and ''reaction time'' for the detection of project-induced changes in hydrologic conditions and ''mitigation adjustments'' are misstated in the Service's emergency listing rule (87 FR 20336; April 7, 2022) based on input from the expert panel that was indicative of a lack of understanding of the monitoring plan, including its utility

as a ''rapid response mechanism,'' the locations and frequency of monitoring, and ''thresholds'' and ''triggers'' established under the November Monitoring and Mitigation Plan. The commenters described the November Monitoring and Mitigation Plan as a hydrologic monitoring network that will be among the most intensive localized monitoring programs in the western United States and noted that it consists of a range of mitigation options, including, if necessary, cessation of geothermal fluid extraction and injection.

Our Response: We have concluded that the success of the mitigation options described in the November Monitoring and Mitigation Plan are highly uncertain given the likelihood and uncertainties of timely and effective detection of project impacts to the springs through the proposed monitoring, and timely recovery of the springs/wetlands complex following any steps taken to remedy impacts. Our conclusions are based on a number of considerations, including, but not limited to: (a) the concentration of the planned monitoring and mitigation thresholds and triggers in the springs/wetland habitat itself, which provide no early warning of the spreading of project effects to the habitat for the Dixie Valley toad (irrespective of the frequency or density of monitoring); and (b) compounded by a delay in the recovery of the hydrologic system following, in this case, implementation of any mitigation measures involving changes in the location(s) or rate(s) of project pumping or injection (Bredehoeft 2011, entire), which will be of finite but unknown length and is not recognized or acknowledged in the November Monitoring and Mitigation Plan. We note that the November Monitoring and Mitigation Plan is an adaptive management document that contemplates further refinement of thresholds and triggers and may be modified further in the future. The best available information at this time is that the monitoring and mitigation plan is not adequate to protect the species from extinction due to geothermal development in Dixie Valley.

(24) *Comment:* One commenter stated that the expert panel did not have access to the November Monitoring and Mitigation Plan, which included refinements to the hydrogeologic characterization of Dixie Valley and their hydrogeologic conceptual model of the Dixie Meadows site. The commenter suggests this caused the panelists to be influenced by their previously held assumptions about the hydrogeology of Dixie Valley, which then influenced their opinions regarding the potential impacts of the project.

Our Response: The November Monitoring and Mitigation Plan contains information about the hydrogeology of geothermal systems in Dixie Valley (broadly) that was widely available in published sources to the expert panel. The panel was composed of expert-level groundwater hydrologists/hydrogeologists and a geologist, the latter among the foremost experts on geothermal systems in Nevada. The November Monitoring and Mitigation Plan did not include significant additional data supporting the proposed hydrogeologic conceptual model for the Dixie Meadows site and significant uncertainty remains regarding the primary and/or significant source or sources of the thermal springs. This uncertainty, in turn, has significant ramifications for the effectiveness of the proposed monitoring plan and any mitigation measures that involve changes to the location(s) or rate(s) of geothermal fluid extraction and/or injection, or ceasing them altogether as stipulated in BLM's Decision Record.

(25) *Comment:* One commenter stated that the proposed listing rule (87 FR 20374; April 7, 2022) included unsupported speculation and surmise, especially regarding the Dixie Valley toad's habitat needs and potential geothermal impacts to its habitats. The commenter disagreed with our assessment of the toad's habitat requirements and potential impacts to the habitat from the geothermal project.

Our Response: We considered the best scientific and commercial data available regarding the Dixie Valley toad to evaluate its potential status under the Act. We solicited peer review of our evaluation of the available data, and our peer reviewers supported our analysis. Science is a cumulative process, and the body of knowledge is ever-growing. In light of this, the Service continually takes new research into consideration. If plausible and significant new research supports amendment or revision of this rule in the future, the Service will consider modifying the rule consistent with the Act as appropriate.

We address the habitat requirements of the Dixie Valley toad in section 3.3 of the SSA report and the potential impacts from geothermal development in section 4.2.1 of the SSA report.

(26) *Comment:* In discussing sufficient wetted area, one commenter stated that in the materials provided to the expert panelists, a USGS study (Huntington et al. 2014, pp. 40–49) indicated the average proportion of hot geothermal water mixing with cooler basin-fill groundwater in Dixie Valley was 10 to 12 percent, although three of the hotter temperature springs had 22 to 31 percent mixing. The commenter stated that in the unlikely event that all geothermal input to the hot springs ceased, 70 to 90 percent of the spring discharge would continue, so a complete loss of habitat postulated by the Service does not seem plausible. Additionally, the commenter stated that although there is a correlation between hot spring discharge, wetted area, and toad habitat, a complete loss of habitat would not occur, especially if only a small variation in hot spring discharge occurred. The commenter referenced table 3.3 in the SSA report to show that there is already a large natural variation in springflow from individual springs.

Our Response: Multiple members of the expert panel suggested that changes in surface expression of springs could occur well before 100 percent of the geothermal input was lost (Service 2022, appendix B), leading to the range of plausible values reported by the panel. Additionally, a complete loss of the geothermal fluid component of the spring discharges would result in a significant decrease in the temperature of waters within the springs/wetlands complex with potentially substantial negative impacts to the Dixie Valley toad.

(27) *Comment:* One commenter stated that the SSA report does not provide evidence to support the conclusion that thermally heated waters are essential or required for toad habitat or reproduction.

Our Response: Section 3.3.2 of the SSA report discusses adequate water temperature needs of the Dixie Valley toad. Two studies (Halstead et al. 2021, entire; Rose et al. 2022, entire) establish the importance of thermal waters to Dixie Valley toads. We considered the best scientific and commercial data available regarding the Dixie Valley toad to evaluate their potential status under the Act. We solicited peer review of our evaluation of the available data, and the peer reviewers supported our analysis.

(28) *Comment:* One commenter discussed how toad sightings in Dixie Meadows from 2009 to 2014 (displayed in figure 4.7 in the SSA report) show that the toads are distributed throughout the spring-fed wetlands but avoid hot water. The commenter stated that many toads were observed near Spring Complex 6, the coldest area, which has a temperature ranging from 12.7 to 15 °C (55 to 59 °F), and there were no toads observed near springs that have a temperature greater than 35 °C (95 °F). The commenter concludes that the need for hot water is unlikely.

Our Response: Section 3.3.2 of the SSA report discusses adequate water temperature preferred by Dixie Valley toads throughout annual seasonal changes. Figure 4.7 in the SSA report depicts toad use between 2009–2014 during April and May (breeding season) of wetted habitat. The Dixie Valley toad uses different parts of the wetlands during different times of the year. Because figure 4.7 shows toad use of the wetlands during the breeding season only and is not representative of all the areas the toad uses throughout the year, it is not appropriate to use figure 4.7 to discuss the toad's preference for warm water. Instead, please refer to figure 5.1 of the SSA report, which is a more accurate description of occupied habitat and shows the Dixie Valley toad occurs near spring heads. Additionally, the thermal needs of the Dixie Valley toad have been established (Halstead et al. 2021, entire; Rose et al. 2022, entire).

Spring Complex 6 is isolated from the other spring complexes and is the southern-most wetland within Dixie Meadows. While toads can be found in this spring complex, many survey attempts in this area are unsuccessful in finding toads and when they are found, few individuals are located. Few individuals are found in Spring Complex 6 because it has water temperatures cooler than the water temperatures preferred by the toad, making it lower-quality habitat. Therefore, although Dixie Valley toads can be found in cooler spring complexes, they are low-quality habitat and do not provide for the needs of the species. We conclude that the low abundance of Dixie Valley toads in Spring Complex 6 supports our conclusion that thermal waters are an essential element of the species' continued existence.

(29) *Comment:* One commenter stated that employees of Ormat have observed tadpoles in ephemeral ponds that fill after storm events that have no thermal-water input, indicating that hot spring input is also unnecessary for hatching.

Our Response: Dixie Valley toad larvae need warm water temperatures for survival. Dixie Valley toad larvae have been found in water temperatures ranging from 20–28 °C (68–82 °F) (Rose et al. 2022, entire) and have been found close to spring heads and throughout the wetland complexes (Rose et al. 2022, entire). Some sites where larvae have been found are heated by solar radiation, which may have been the case for the anecdotal observation by Ormat employees. Larvae likely use a combination of sites heated by solar radiation and thermal water input; therefore, reduction in thermal-water input will decrease habitat for a life stage with an already highly restricted amount of habitat.

(30) *Comment:* One commenter disagrees with the correlation between thermal characteristics of the Dixie Valley toad habitat and disease resistance to chytridiomycosis.

Our Response: Section 4.2.8 in the SSA report describes potential disease impacts from chytridiomycosis and the role that water temperature plays in the establishment and severity of chytridiomycosis. The best available information indicates that the thermal nature of Dixie Valley toad habitat may keep chytrid fungus from becoming established; therefore, it is imperative that the water maintains its natural thermal characteristics (Forrest et al. 2013, pp. 75–85; Halstead et al. 2021, pp. 33–35).

(31) *Comment:* One commenter stated that because ambient temperatures in Dixie Valley are frequently higher than 25 °C (77 °F), our assertion that it is imperative to maintain precise spring-water temperatures is lacking in support.

Our Response: Available information does not support the assumption that warm air temperatures will keep water temperatures high regardless of effects from geothermal production. Spring complexes 2, 3, 4, and 5 (which provide a majority of the wetland habitat for the Dixie Valley toad) produce water temperatures greater than 25 °C (77 °F); thus, ambient air temperature would not be able to warm water temperatures sufficiently. In addition, the commenter only references high temperatures in Dixie Valley. If water temperatures in the springs are decreased by geothermal production, then winter months with colder ambient air temperatures could cool water temperatures to unsuitable levels. In summary, the springs are naturally warmer than air temperatures because of the geothermal conditions, and if the geothermal conditions are removed, the ambient air temperatures would be insufficient to raise the water temperatures to the temperatures required by the Dixie Valley toad for reproduction and survival.

(32) *Comment:* One commenter stated that there is a wide range in values for total dissolved solids, dissolved oxygen, and pH across Dixie Valley toad aquatic habitat. The commenter asserts that the SSA report does not provide evidence that there is a correlation between toad distribution and changes in water quality.

Our Response: The Service recognizes that the exact water-quality parameters preferred by Dixie Valley toads are unknown and should be studied further. However, after review of the best available information, we conclude this species has evolved only in Dixie Meadows and is presumed to thrive in the current existing complex mix of water emanating from both the basin-fill aquifer and the deep geothermal reservoir. See section 3.3.4 of the SSA report for more information regarding adequate water quality.

(33) *Comment:* One commenter stated that there is no evidence for the SSA report's description that the piedmont fault is the source of both the cold and hot springs at Dixie Meadows, and that information was not provided to the expert panel regarding the presence of the basin-fill hydrothermal plume located west of the springs. Additionally, the alternative hypothesis regarding the source of the springs or other interpretations of the hydrologic significance of the piedmont fault were not provided to the expert panelists. The commenter then stated that, due to this omission, the panelists were not provided with the best available scientific information.

Our Response: We agree that the Piedmont fault is not the source of both cold basin-fill waters and geothermal fluids discharging from the springs, subsequently, we revised the SSA report to correct that error. Based on the chemistry of waters discharging from the thermal springs, we interpret them to be mixtures, to various degrees, of geothermal fluids and basin-fill groundwaters (Huntington et al. 2014, entire), including those flowing west to east from the foot of the mountains toward the springs within the long-recognized basin-fill hydrothermal plume.

In regards to the expert panel, the panelists were composed of expert groundwater hydrologists, hydrogeologists, and geologists, including one of the foremost experts on geothermal systems in Nevada, who are aware of the existence of the basin-fill hydrothermal plume and Piedmont fault and their potential roles as sources of waters discharging from the springs.

(34) *Comment:* One commenter stated that the literature used by the Service stating that geothermal energy production is the greatest threat to Dixie Valley toads is flawed because some of the scientific papers cited did not have the requisite hydrogeological analysis to support that assertion. The commenter specifically pointed to Forrest et al. (2017), Gordon et al. (2017), and Halstead et al. (2021).

Our Response: We considered the best scientific and commercial data available regarding the Dixie Valley toad to evaluate the species' potential status

under the Act. We solicited peer review of our evaluation of the available data, and our peer reviewers supported our analysis. All three papers mentioned by the commenter are peer-reviewed journal articles. The authors of the three papers provided important information on the biology, habitat requirements, and use by the Dixie Valley toad within the Dixie Meadow wetlands. All three papers came to the same conclusion that geothermal development was the greatest threat to the persistence of the toad as described in section 4.2.1 of the SSA report. This conclusion was further supported by the expert panel and our own analysis of the threats facing the Dixie Valley toad.

(35) *Comment:* One commenter stated that the Service recognized that every geothermal site is unique, but then considered the impacts of geothermal energy projects at four other sites in California and Nevada as indicative of the likely impacts of the Dixie Meadows project, without analyzing the differences between those projects and the one planned at Dixie Meadows, with particular consideration given to impacts that have occurred at the Jersey Valley site.

Our Response: Other geothermal projects were used to inform the range of plausible outcomes, but characteristics of projects were not directly applied to the Dixie Meadows project, nor were they used to determine a most likely outcome. In addition, the expert panelists discussed differences in technology and site characteristics between other geothermal projects and the Dixie Meadows project when forming their opinions (Service 2022, appendix A). The expert panelists used these comparisons to narrow down the range of plausible outcomes of the Dixie Meadows project, subsequently incorporating the differences between other geothermal projects and this project into our analysis.

(36) *Comment:* One commenter stated that the expert panelists questioned whether those responsible for managing the power plant operation would implement the mitigation measures outlined in the January Monitoring and Mitigation Plan if/when the measures are counter to operational goals. This viewpoint likely influencing the panelists' opinions regarding the potential impacts of the project, despite the information provided in the November Monitoring and Mitigation Plan.

Our Response: The expert panel had access to the January Monitoring and Mitigation Plan, which substantially described the monitoring and mitigation measures, hypotheses concerning the hydrogeology of the Dixie Meadows site and source(s) of geothermal fluids discharging from the springs, and mitigation measures (including significant curtailments of project operations) outlined in the November Monitoring and Mitigation Plan. Based on the panelists' evaluation of the above, as well as other published information about the hydrogeology and surface water resources of the Dixie Meadows site, they collectively expressed low confidence in the ability of the January Monitoring and Mitigation Plan to detect and mitigate project-induced changes in the temperature and/or flow of the springs because of the hydrogeologic complexity and natural hydrologic variability of the site, limited baseline data, inadequacies in the proposed monitoring and mitigation options, and potential interacting effects of climatic change and other groundwater-related uses in the valley. After the experts expressed low confidence in the ability of the January Monitoring and Mitigation Plan to detect and mitigate changes to the springs and wetland complex, they additionally expressed concern that mitigation measures might not be implemented if the measures ran counter to operational goals. Therefore, although the panelists' concern about mitigation measures being implemented was one factor, the other factors discussed above had a greater influence on the experts' judgements.

(37) *Comment:* One commenter claimed that the Service did not consider instances where geothermal energy projects have had negligible to no impacts on springs or other surface discharges, including the geothermal energy projects at the Tungsten Mountain Power Plant and McGinness Hills facility in Nevada and the 110–MW Ngatamariki geothermal project in New Zealand. The commenter additionally stated that a condition of approval of the Ngatamariki project was an agreement to preserve surface geothermal features within the Orakei Karako thermal system to the northeast.

Our Response: The expert elicitation panel considered all of these projects in their discussions, with the McGinness Hills project referenced in the elicitation record (Service 2022, appendix A). The Service considered, as part of the expert elicitation and SSA, impacts (or the lack thereof) to surface water resources experienced at other geothermal energy production in evaluating the potential impacts of the project planned at Dixie Meadows. We find that all the other geothermal energy projects referenced by the commenter have important differences from the Dixie Meadows site, such that we find that it is not scientifically supportable to extrapolate their effects to the Dixie Meadows project.

The hydrogeology of the Dixie Meadows site differs significantly from that at the McGinness Hills, Tungsten Mountain, and Ngatamariki sites in that the Dixie Meadows springs are not hydraulically isolated from the underlying geothermal reservoir by one or more low permeability layers; *e.g.,* clay or clay-rich strata. Consequently, unlike surface water resources at the McGinness Hills, Tungsten Mountain, and Ngatamariki sites, the Dixie Meadows springs can be impacted by production pumping and/or injection in the underlying geothermal reservoir. Additionally, the best available information suggests that no hydraulic connection exists between the Orakei Korako geothermal system and the Ngatamariki site (O'Brien 2010, p. iii). Please refer to section 4.2.1 of the SSA report for further discussion.

(38) *Comment:* One commenter stated that the basin-fill hydrothermal plume is the only source of geothermal fluids discharging from the springs and, as a result, spring flows, including their temperatures, could be maintained by reinjecting some of the available cooled geothermal fluids into the plume; which could additionally result in an increase in the volume of the spring flows. In this respect, the Dixie Meadows site/resource is different than other geothermal projects cited in the proposed and emergency listing rules (87 FR 20374 and 87 FR 20336, both published on April 7, 2022).

Our Response: It is clear from the presence of a major fault scarp just west of the springs (at the location of the Piedmont fault) that surficial groundwaters flowing west to east through the basin fill, including the long-recognized hydrothermal plume (Bergman et al. 2014, pp. 74 and 93), contribute to the spring flows; and that the cold water component of the basin-fill hydrothermal plume varies seasonally and is largely controlled by climatic factors. Additionally, the Piedmont fault may be a significant, if not the primary, source of geothermal fluids discharging from the springs, a matter of dispute (Bergman et al. 2014, entire). The relative contributions of these two potential sources, the basin-fill hydrothermal plume and Piedmont fault, to the flow and temperatures of the springs are unknown.

Due to the variable cold-water contribution of the basin-fill hydrothermal plume to the discharge and temperatures of the springs, which is largely driven by climatic factors

(including seasonal variations, such as the amount and timing of snowmelt), as well as the unspecified location(s), rate(s), and timing of the described reinjection of cooled geothermal fluids into the plume, we have low confidence that the measure described by the commenter could be used to reproduce the temperatures and flow rates of various springs at Dixie Meadows.

Likewise, any resulting increases in the flow of the springs are likely to be accompanied by a decrease in the temperature of the springs (in that sense, a depletion of the spring flows).

Regarding the geologic (and hydrogeologic) characteristics of the Dixie Meadows site, it is not unique among the geothermal energy project sites considered in the emergency listing rule (87 FR 20336; April 7, 2022). The Dixie Valley Power Plant site in northern Dixie Valley is situated within the same Dixie Valley Fault Zone with many of the same major faults; a hydrothermal plume also exists within the overlying basin fill at that site. One or more thermal springs were once present in the vicinities of the Steamboat Springs and Jersey Valley geothermal projects, also referenced in the emergency listing rule.

(39) *Comment:* One commenter stated that there will be no net depletion of water within the overall hydrologic/hydrogeologic system because consumptive use of the geothermal fluids will be negligible.

Our Response: We agree the overall water balance of the larger (area-wide) hydrologic/hydrogeologic system may not be affected to any significant degree by the combined geothermal extraction and injection during operations due to the use of binary technology within the power plant. However, the transport of geothermal fluids to the springs, which ultimately depends on the movement of geothermal fluids along discrete permeable structures in faulted/fractured bedrock, may be altered by the project pumping and/or injection in ways that cannot be anticipated in this fractured-rock environment; impacting, in particular, the temperatures of the springs, despite maintenance of the overall water balance within the system. Because water temperature is a key component of Dixie Valley toad survival and reproduction, we are most concerned about the impacts of the project on water temperatures within the toad's habitat.

(40) *Comment:* One commenter stated that the hydrogeology of the Dixie Meadows site, including the geothermal reservoir, is unique; reasonably well understood and defined based on exploration drilling, flow testing, and spring analyses conducted to date; and not comparable to other geothermal systems in Dixie Valley or elsewhere in the region.

Our Response: The hydrogeology of the geothermal system at Dixie Meadows has many geologic, hydrogeologic, and thermal characteristics in common with other geothermal systems/cells identified and studied on the west side of Dixie Valley within the Dixie Valley Fault Zone (area of the Comstock Mine and long-time Dixie Valley Power Plant) based on geothermal investigations beginning in the 1960s (Bergman et al. 2014, entire), including the presence of basin-fill hydrothermal plumes emanating from the vicinity of the range-bounding Dixie Valley Fault. In addition to the Dixie Valley Power Plant site, one or more thermal springs were once present in the vicinities of the Steamboat Springs and Jersey Valley geothermal projects, also referenced in the emergency listing rule (87 FR 20336; April 7, 2022).

The distinguishing (unique) feature of the Dixie Meadows geothermal system is the presence of numerous thermal springs, numbering well in excess of 20, that provide habitat for an endemic species, the Dixie Valley toad. With respect to the current understanding of the geothermal system/site, its hydrogeology is poorly characterized to date, due, in particular, to limited bedrock exploratory drilling and field-scale multi-well pumping and injection testing. This paucity of information hinders the development of a conceptual hydrogeologic model that includes identification/confirmation of the source(s) of the thermal spring discharges, as well as the development of an effective early-warning monitoring program and mitigation measures, both of which depend on the identification of the source(s) of the thermal spring discharges.

I. Final Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the Dixie Valley toad (*Anaxyrus williamsi*) is presented in the SSA report (Service 2022, entire).

The Dixie Valley toad was described as a distinct species in the western toads (*Anaxyrus boreas*) species complex in 2017, due to morphological differences, genetic information, and its isolated distribution (Gordon et al. 2017, entire). Forrest et al. (2017, entire) also published a paper describing Dixie Valley toad and came up with similar results but stopped short of concluding that it is a unique species. We evaluated both papers and concluded the Gordon et al. (2017, entire) paper provided a better sampling design to answer species-level genetic questions and conducted a more thorough morphological analysis. Additionally, the Dixie Valley toad has been accepted as a valid species by the two leading authoritative amphibian internet sites: (1) amphibiaweb.org (AmphibiaWeb 2022, website) and (2) Amphibian Species of the World (Frost 2021, website). Because both the larger scientific community and our own analysis of the best available scientific information indicate that the findings of Gordon et al. (2017 entire) are well supported, we are accepting their conclusions that the Dixie Valley toad is a unique species (*Anaxyrus williamsi*). Therefore, we have determined that the Dixie Valley toad is a listable entity under the Act.

Limited information is available specific to the life history of the Dixie Valley toad; therefore, closely associated species are used as surrogates where appropriate. Breeding (denoted by observing a male and female in amplexus, egg masses, or tadpoles) occurs annually between March and May (Forrest 2013, p. 76). Breeding appears protracted due to the thermal nature of the habitat and can last up to 3 months (March–May), with toads breeding early in the year in habitats closer to the thermal spring sources and then moving downstream into habitats as they warm throughout spring and early summer. Other toad species typically have a much more contracted breeding season of 3 to 4 weeks (*e.g.,* Sherman 1980, pp. 18–19, 72–73). Dixie Valley toad tadpoles hatch shortly after being deposited; time to hatching is not known but is likely dependent on water temperature (*e.g.,* black toad (*Anaxyrus exsul*) tadpoles hatch in 7 to 9 days; Sherman 1980, p. 97). Fully metamorphosed Dixie Valley toadlets were observed 70 days after egg laying (Forrest 2013, pp. 76–77).

The Dixie Valley toad is a narrow-ranging endemic (highly local and known to exist only in their place of origin) known from one population in the Dixie Meadows area of Churchill County, Nevada. The species occurs primarily on Department of Defense (Fallon Naval Air Station) lands (90 percent) and Bureau of Land Management (BLM) lands (10 percent). The wetlands located in Dixie Meadows cover 307.6 hectares (ha) (760 acres (ac)) and are fed by geothermal springs. The potential area of occupancy is estimated to be 146 ha (360 ac) based on the extent of wetland-associated vegetation. The species is heavily reliant on these

wetlands, as it is rarely encountered more than 14 meters (m) (46 feet (ft)) from aquatic habitat (Halstead et al. 2021, p. 7).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for threatened and endangered species. In 2019, jointly with the National Marine Fisheries Service, the Service issued final rules that revised the regulations in 50 CFR parts 17 and 424 regarding how we add, remove, and reclassify threatened and endangered species and the criteria for designating listed species' critical habitat (84 FR 45020 and 84 FR 44752; August 27, 2019). At the same time the Service also issued final regulations that, for species listed as threatened species after September 26, 2019, eliminated the Service's general protective regulations automatically applying to threatened species the prohibitions that section 9 of the Act applies to endangered species (collectively, the 2019 regulations).

As with the proposed rule, we are applying the 2019 regulations for this final rule because the 2019 regulations are the governing law just as they were when we completed the proposed rule. Although there was a period in the interim—between July 5, 2022, and September 21, 2022—when the 2019 regulations became vacated and the pre-2019 regulations therefore governed, the 2019 regulations are now in effect and govern listing and critical habitat decisions (*see Center for Biological Diversity* v. *Haaland,* No. 4:19-cv-05206–JST, Doc. 168 (N.D. Cal. July 5, 2022) (CBD v. Haaland) (vacating the 2019 regulations and thereby reinstating the pre-2019 regulations)); *In re: Cattlemen's Ass'n,* No. 22–70194 (9th Cir. Sept. 21, 2022) (staying the district court's order vacating the 2019 regulations until the district court resolved a pending motion to amend the order); *Center for Biological Diversity* v. *Haaland,* No. 4:19-cv-5206–JST, Doc. Nos. 197, 198 (N.D. Cal. Nov. 16, 2022) (granting plaintiffs' motion to amend July 5, 2022 order and granting government's motion for remand without vacatur). The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species (Service 2022, entire). The SSA report does not represent our decision on whether the species should be listed as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R8–ES–2022–0024 on *https://www.regulations.gov.*

To assess the Dixie Valley toad's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer

and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We used this information to inform our regulatory decision.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

Species Needs

Wetted Area

Dixie Meadows contains 122 known spring and seep sources and discharges approximately 1,109,396 cubic meters per year (m^3/yr) (900 acre-feet per year (afy)) (BLM 2021b, appendix H, pp. 1–2), which distributes water across the wetland complex then flows out to the playa or is collected in a large ephemeral pond in the northeast portion of the wetland complex. Some of the larger springs have springbrooks that form channels while in other areas the water spreads out over the ground or through wetland vegetation creating a thin layer of water or wet soil that helps maintain the wetland. Spring discharge is inherently linked to the amount of wetted area within the wetland complex. Spring discharge is important for the viability of the Dixie Valley toad because changes to discharge rates likely impact the ability of the toad to survive in a particular spring complex.

Dixie Valley toad is a highly aquatic species rarely found more than 14 m (46 ft) away from water (Halstead et al. 2021, pp. 28, 30). The species needs wetted area for shelter, feeding, reproduction, and dispersal. Any change in the amount of wetted area will directly influence the amount of habitat available to the Dixie Valley toad. Due to the already restricted range of the habitat, the species needs to maintain the entirety of the 1.46-square-kilometer (km^2) (360-ac) potential area of occupancy, based on the extent of the wetland-associated vegetation.

Adequate Water Temperature

In addition to the Dixie Valley toad being highly aquatic, the temperature of the water is also important to its life history. The species needs warm temperatures for shelter and reproduction. The Dixie Valley toad selects water or substrate that is warmer compared to nearby random paired locations, particularly in spring, fall, and winter months (Halstead et al. 2021, pp. 30, 33–34). During spring, they select areas with warmer water for breeding (oviposition sites), which allows for faster egg hatching and time to metamorphosis (Halstead et al. 2021, pp. 30, 33–34). During fall, they select warmer areas (closer to thermal springs with dense vegetation), which satisfies their thermal preferences as nighttime temperatures decrease (Halstead et al. 2021, pp. 30, 33–34). As winter approaches, toads find areas with consistent warm temperatures during brumation (hibernation for cold-blooded animals), so they do not freeze (Halstead et al. 2021, pp. 30, 33–34). This affinity for warm water temperature during brumation is unique to the Dixie Valley toad as compared to other species within the western toad species complex, which select burrows, rocks, logs, or other structures to survive through winter (Browne and Paszkowski 2010, pp. 53–56; Halstead et al. 2021, p. 34). Therefore, although the exact temperatures are unknown (range between 10–41 °C (50–106 °F), Dixie Valley toad requires water temperatures warm enough to successfully breed and survive colder months during the year.

Wetland Vegetation

The most common wetland vegetation found within Dixie Meadows includes *Juncus balticus* (Baltic rush), *Schoenoplectus* spp. (bulrushes), *Phragmites australis* (common reed), *Eleocharis* spp. (spikerushes), *Typha* spp. (cattails), *Carex* spp. (sedges), and *Distichlis spicata* (saltgrass) (AMEC Environment and Infrastructure 2014, p. I–1; Tierra Data 2015, pp. 2–25–2–29; BLM 2021b, appendix H, pp. 50–52, 93–99). Several species of invasive and nonnative plants also occur in Dixie Meadows, including *Cicuta maculata* (water hemlock), *Cardaria draba* (hoary cress), *Lepidium latifolium* (perennial pepperweed), *Elaeagnus angustifolia* (Russian olive), and *Tamarix ramosissima* (saltcedar) (AMEC Environment and Infrastructure 2014, p. 3–59). The Dixie Valley toad needs sufficient wetland vegetation to use as shelter. At a minimum, maintaining the current heterogeneity of the wetland vegetation found in Dixie Meadows is a necessary component for maintaining the resiliency of the Dixie Valley toad (Halstead et al. 2021, p. 34).

Adequate Water Quality

Amphibian species spend all or part of their life cycle in water; therefore, water quality characteristics directly affect amphibians. Dissolved oxygen, potential hydrogen (pH), salinity, water conductivity, and excessive nutrient concentrations (among other water quality metrics) all have direct and indirect impacts to the survival, growth, maturation, and physical development

of amphibian species when found to be outside of naturally occurring levels for any particular location (Sparling 2010, pp. 105–117).

Various water quality data have been collected from a few springs within Dixie Meadows and from wells drilled during geothermal exploration activities (BLM 2021b, appendix H, pp. 57–64). The exact water quality parameters preferred by the Dixie Valley toad are unknown; however, this species has evolved only in Dixie Meadows and is presumed to thrive in the current existing, complex mix of water emanating from both the basin-fill aquifer and the deep geothermal reservoir. Within the unique habitat in Dixie Meadows, and given the life history and physiological strategies employed by the species, a good baseline of existing environmental water quality factors that are most important for all life stages should be studied (Rowe et al. 2003, p. 957). The Dixie Valley toad needs the natural variation of the current water quality parameters found in Dixie Meadows to maintain resiliency.

Threats Analysis

We reviewed the potential risk factors (*i.e.,* threats, stressors) that may be currently affecting the Dixie Valley toad. In this rule, we discuss only those factors in detail that could meaningfully affect the status of the species.

The primary threats affecting the status of the Dixie Valley toad are geothermal development and associated groundwater pumping (Factor A); establishment of *Batrachochytrium dendrobatidis* (*Bd;* hereafter referred to as amphibian chytrid fungus), which causes the disease chytridiomycosis (Factor C); predation by the invasive American bullfrog (*Lithobates catesbeianus*) (Factor C); groundwater pumping associated with human consumption, agriculture, and county planning (Factor A); and climate change (Factor A). Climate change may further influence the degree to which these threats, individually or collectively, may affect the Dixie Valley toad. The risk factors that are unlikely to have significant effects on the Dixie Valley toad, such as livestock grazing and historical spring modifications, are not discussed here but are evaluated in the current condition assessment of the SSA report.

Geothermal Development

Geothermal resources are reservoirs of hot water or steam found at different temperatures and depths below the ground. These geothermal reservoirs can be used to produce energy by drilling a well and bringing the heated water or steam to the surface. Geothermal energy plants use the steam or heat created by the hot water to drive turbines that produce electricity. Three main technologies are being used today to convert geothermal water into electricity: dry steam, flash steam, and binary cycle. Binary technology is the focus for this analysis because that type of geothermal power technology has been approved for development at Dixie Meadows.

Binary cycle power plants use the heat of geothermal fluids extracted from (pumped out of) geothermal reservoirs to heat a secondary fluid (*e.g.,* butane) that generally has a much lower boiling point than water. This process is accomplished through a heat exchanger, and the secondary fluid is flashed into vapor by the heat from the geothermal fluid; the vapor then drives the turbines to generate electricity. The cooled geothermal fluid is subsequently reinjected back into the ground to maintain pressures within the geothermal reservoir and to be reheated, incurring for all practical purposes no losses to evaporation. Consequently, binary cycle power plants do not affect the overall amount of water within the hydrologic system or, optimally, pressures within the geothermal reservoir (despite the project pumping). However, in the case of the Dixie Meadows site, the transport of geothermal fluids to the springs, which ultimately depends on the movement of geothermal fluids along discrete permeable structures in faulted/fractured bedrock, may be altered by the project pumping and/or injection at specific locations in ways that cannot be anticipated in this fractured-rock environment; impacting, in particular, the temperatures of the springs, despite maintenance of the overall water balance within the system.

General impacts from geothermal production facilities are presented below. Because every geothermal field is unique, it is difficult to predict what effects from geothermal production may occur.

Prior to geothermal development, the flow path of water underneath the land surface is usually not known with sufficient detail to understand and prevent impacts to the surface wetlands dependent upon those flows (Sorey 2000, p. 705). Changes in surface waters connected to underground thermal waters as a result of geothermal production are common and are expected. Typical changes seen include changes in water temperature, flow, and water quality, which are all resource needs of the Dixie Valley toad that could be negatively affected by geothermal production (Sorey 2000, entire; Bonte et al. 2011, pp. 4–8; Kaya et al. 2011, pp. 55–64; Chen et al. 2020, pp. 2–6).

Steam discharge, land subsidence (*i.e.,* gradual settling or sudden sinking of the ground surface due to the withdrawal of large amounts of groundwater), and changes in water temperature and flow have all been documented from geothermal production areas throughout the western United States (Sorey 2000, entire). For example:

(1) Long Valley Caldera near Mammoth, California. Geothermal pumping in the period 1985–1998 resulted in several springs ceasing to flow and declines in pressure of the geothermal reservoir, which caused reductions of 10–15 °C (50–59 °F) in the reservoir temperature and a localized decrease of approximately 80 °C (176 °F) near the reinjection zone (Sorey 2000, p. 706).

(2) Steamboat Springs near Reno, Nevada. Geothermal development resulted in the loss of surface discharge (geysers and springs) on the main terrace and a reduction of thermal water discharge to Steamboat Creek by 40 percent (Sorey 2000, p. 707).

(3) Northern Dixie Valley near Reno, Nevada. Steam discharge and land subsidence occurred at an existing 56–MW geothermal plant in northern Dixie Valley, Nevada, which has been in production since 1985 (Sorey 2000, p. 708; Huntington et al. 2014, p. 5). To remedy the subsidence, the plant began pumping water from the cold basin fill aquifer (local aquifer) and reinjecting it above the hot geothermal reservoir (regional aquifer) (Huntington et al. 2014, p. 5). This approach may have led to other detrimental impacts as the depth to groundwater increased from 1.8 m (6 ft) in 1985 to 4.3–4.6 m (14–15 ft) in 2009–2011 (Albano et al. 2021, p. 78).

(4) Jersey Valley near Reno, Nevada. In 2011, a 23.5–MW geothermal power plant started production in Jersey Valley, just north of Dixie Valley. Springflow at a perennial thermal spring began to decline almost immediately after the power plant began operation (BLM 2022, p. 1; Nevada Division of Water Resources (NDWR) 2022, unpublished data). By 2014, the Jersey Valley Hot Spring ceased flowing (BLM 2022, p. 1; NDWR 2022, unpublished data). The loss of aquatic insects from the springbrook has diminished the foraging ability of eight different bat species that occur in the area (BLM 2022, p. 28). To mitigate for the spring going dry, the BLM proposed to pipe

geothermal fluid to the spring source (BLM 2022, p. 8); however, mitigation has not yet occurred. If a similar outcome were to occur in Dixie Meadows, resulting in the complete drying of the springs, the Dixie Valley toad would likely be extirpated if mitigation to prevent the drying of the springs is not satisfactorily or timely achieved.

In an effort to minimize changes in water temperature, quantity, and quality, and to maintain pressure of the geothermal reservoir, geothermal fluids are reinjected into the ground, although reinjected water is at a lower temperature than when it was pumped out of the ground. This practice entails much trial and error in an attempt to equilibrate subsurface reservoir pressure. It can take several years to understand how a new geothermal field will react to production and reinjection wells; however, reinjection does not always have the desired effect (Kaya et al. 2011, pp. 55–64).

Geothermal energy production is considered the greatest threat to the persistence of Dixie Valley toad (Forrest et al. 2017, pp. 172–173; Gordon et al. 2017, p. 136; Halstead et al. 2021, p. 35). Geothermal environments often harbor unique flora and fauna that have evolved in these rare habitats (Boothroyd 2009, entire; Service 2019, entire). Changes to these rare habitats often cause declines in these endemic organisms or even result in the destruction of their habitat (Yurchenko 2005, p. 496; Bayer et al. 2013, pp. 455–456; Service 2019, pp. 2–3). Because the Dixie Valley toad relies heavily on wetted area and warm water temperature to remain viable, reduction of these two resource needs could cause significant declines in the population and changes to its habitat that are detrimental to the species and result in it being in danger of extinction.

Disease

Over roughly the last four decades, pathogens have been associated with amphibian population declines, mass die-offs, and extinctions worldwide (Bradford 1991, pp. 174–176; Muths et al. 2003, pp. 359–364; Weldon et al. 2004, pp. 2,101–2,104; Rachowicz et al. 2005, pp. 1,442–1,446; Fisher et al. 2009, pp. 292–302; Knapp et al. 2011, pp. 8–19). One pathogen strongly associated with dramatic declines on all continents that harbor amphibians is chytridiomycosis caused by amphibian chytrid fungus (Rachowicz et al. 2005, pp. 1,442–1,446). Chytrid fungus has now been reported in amphibian species worldwide (Fellers et al. 2001, pp. 947–952; Rachowicz et al. 2005, pp. 1,442–1,446). Early doubt that this particular pathogen was responsible for worldwide die-offs has largely been overcome by the weight of evidence documenting the appearance, spread, and detrimental effects to affected populations (Vredenburg et al. 2010, pp. 9,690–9,692).

Clinical signs of chytridiomycosis and diagnosis include abnormal posture, lethargy, and loss of righting reflex (the ability to correct the orientation of the body when it is not in its normal upright position) (Daszak et al. 1999, p. 737). Chytridiomycosis also causes gross lesions, which are usually not apparent and consist of abnormal epidermal sloughing and ulceration, as well as hemorrhages in the skin, muscle, or eye (Daszak et al. 1999, p. 737). Chytridiomycosis can be identified in some species of amphibians by examining the oral discs (tooth rows) of tadpoles that may be abnormally formed or lacking pigment (Fellers et al. 2001, pp. 946–947).

Despite the acknowledged impacts of chytridiomycosis to amphibians, little is known about this disease outside of mass die-off events. There is high variability between species of amphibians in response to being infected, including within the western toad species complex. Two long-term study sites have documented differences in apparent survival of western toads between two different sites in Montana and Wyoming (Russell et al. 2019, pp. 300–301). The chytrid-positive western toad population in Montana was reduced by 19 percent compared to chytrid-negative toads in that area—in comparison to the western toad population in Wyoming, which was reduced by 55 percent (Russell et al. 2019, p. 301). Various diseases are confirmed to be lethal to Yosemite toads (*Anaxyrus canorus*) (Green and Sherman 2001, p. 94), and research has elucidated the potential role of chytrid fungus infection as a threat to Yosemite toad populations (Dodge 2013, pp. 6–10, 15–20; Lindauer and Voyles 2019, pp. 189–193). These various diseases and infections, in concert with other factors, have likely contributed to the decline of the Yosemite toad (Sherman and Morton 1993, pp. 189–197) and may continue to pose a risk to the species (Dodge 2013, pp. 10–11; Lindauer and Voyles 2019, pp. 189–193). Amargosa toads (*Anaxyrus nelsoni*) are known to have high infection rates and high chytrid fungus loads; however, they do not appear to show adverse impacts from the disease (Forrest et al. 2015, pp. 920–922). Not all individual amphibians that test positive for chytrid fungus develop chytridiomycosis.

Dixie Valley toad was sampled for chytrid fungus in 2011–2012 (before it was recognized as a species) and 2019–2021 (Forrest 2013, p. 77; Kleeman et al. 2021, entire); chytrid fungus was not found during either survey. However, chytrid fungus has been documented in bullfrogs in Turley Pond, located approximately 10 km south of Dixie Meadows (Forrest 2013, p. 77), and bullfrogs are a known vector species for spreading chytrid fungus and diseases to other species of amphibians (Daszak et al. 2004, pp. 203–206; Urbina et al. 2018, pp. 271–274; Yap et al. 2018, pp. 4–8).

The best available information indicates that the thermal nature of the Dixie Valley toad habitat may keep chytrid fungus from becoming established; therefore, it is imperative that the water maintains its natural thermal characteristics (Forrest 2013, pp. 75–85; Halstead et al. 2021, pp. 33–35). Western toads exposed to chytrid fungus survive longer when exposed to warmer environments (mean 18 °C (64 °F)) as compared to western toads in cooler environments (mean 15 °C (59 °F)) (Murphy et al. 2011, pp. 35–38). Additionally, chytrid fungus zoosporangia grown at 27.5 °C (81.5 °F) remain metabolically active; however, no zoospores are produced, indicating no reproduction at this high temperature (Lindauer et al. 2020, pp. 2–5). Generally, chytrid fungus does not seem to become established in water warmer than 30 °C (86 °F) (Forrest and Schlaepfer 2011, pp. 3–7). Dixie Meadows springhead water temperatures range from 13 °C (55 °F) to 74 °C (165 °F), although the four largest spring complexes (springs that create the largest wetland areas and are inhabited by a majority of the Dixie Valley toad population) range from 16 °C (61 °F) to 74 °C (165 °F) with median temperatures of at least 25 °C (77 °F). Additionally, water temperatures measured in 2019 at toad survey sites throughout Dixie Meadows (*i.e.,* not at springheads) ranged from 10 to 41 °C (50 to 106 °F) (Halstead and Kleeman 2020, entire). Any reduction in water temperature, including reductions caused by geothermal development, would not only affect the ability of Dixie Valley toads to survive during cold months, but could also make the species vulnerable to chytrid fungus.

Predation

Predation has been reported in species similar to the Dixie Valley toad and likely occurs in Dixie Meadows; however, predation of Dixie Valley toads has not been documented. Likely predators on the egg and aquatic larval

forms of Dixie Valley toad include predacious diving beetles (*Dytiscus* spp.) and dragonfly larvae (Odonata). Common ravens (*Corvus corax*) and other corvids are known to feed on juvenile and adult black toads and Yosemite toads (Sherman 1980, pp. 90–92; Sherman and Morton 1993, pp. 194–195). Raven populations are increasing across the western United States and are clearly associated with anthropogenic developments, such as roads and power lines (Coates and Delehanty 2010, pp. 244–245; Howe et al. 2014, pp. 44–46). Ravens are known to nest within Dixie Valley (Environmental Management and Planning Solutions 2016, pp. 3–4).

The American bullfrog, a ranid species native to much of central and eastern North America, now occurs within Dixie Meadows (Casper and Hendricks 2005, pp. 540–541; Gordon et al. 2017, p. 136). Bullfrogs are recognized as one of the 100 worst invasive species in the world (Global Invasive Species Database 2021, pp. 1–17). Bullfrogs are known to compete with and prey on other amphibian species (Moyle 1973, pp. 19–21; Kiesecker et al. 2001, pp. 1,966–1,969; Pearl et al. 2004, pp. 16–18; Casper and Hendricks 2005, pp. 543–544; Monello et al. 2006, p. 406; Falaschi et al. 2020, pp. 216–218).

Bullfrogs are a gape-limited predator, which means they eat anything they can swallow (Casper and Hendricks 2005, pp. 543–544). The Dixie Valley toad is the smallest toad species in the western toad species complex and can easily be preyed upon by bullfrogs. Smaller bullfrogs eat mostly invertebrates (Casper and Hendricks 2005, p. 544) and thus may compete with Dixie Valley toad for food resources. Within Dixie Valley, bullfrogs are known to occur at Turley Pond and in one area of Dixie Meadows adjacent to occupied Dixie Valley toad habitat (Forrest 2013, pp. 74, 87; Rose et al. 2015, p. 529; Halstead et al. 2021, p. 24).

Climate Change

Both human settlements and natural ecosystems in the southwestern United States are largely dependent on groundwater resources, and decreased groundwater recharge may occur as a result of climate change (U.S. Global Change Research Program 2009, p. 133). Furthermore, the human population in the Southwest is expected to increase 70 percent by mid-century (Garfin 2014, p. 470). Resulting increases in urban development, agriculture, and energy-production facilities will likely place additional demands on already limited water resources. Climate change will likely increase water demand and shrink water supply, since water loss may increase evapotranspiration rates and runoff during storm events (Archer and Predick 2008, p. 25).

In order to identify changing climatic conditions more specific to Dixie Meadows, we conducted a climate analysis using the Climate Mapper web tool (Hegewisch et al. 2020, online). The Climate Mapper is a web tool for visualizing past and projected climate and hydrology of the contiguous United States. This tool maps real-time conditions, current forecasts, and future projections of climate information across the United States to assist with decisions related to agriculture, climate, fire conditions, and water.

For our analysis, we analyzed mean annual temperature and percent precipitation using the historical period of 1971–2000 and the projected future time period 2040–2069. We examined emission scenarios that used representative concentration pathways (RCPs) 4.5 and 8.5 using ArcGIS Pro.

Our analysis predicts increased air temperatures in Dixie Meadows, along with a slight increase in precipitation. Annual mean air temperature is projected to increase between 2.5 and 3.4 °C (4.5 and 6.1 °F) and result in average temperatures 3.0 °C (5.3 °F) warmer throughout Dixie Meadows between 2040 and 2069 (Hegewisch et al. 2020, Geographic Information System (GIS) data). Under the two emission scenarios, annual precipitation is projected to increase by 4.5 to 7.7 percent (Hegewisch et al. 2020, GIS data).

Climate change may impact the Dixie Valley toad and its habitat in two main ways: (1) reductions in springflow as a result of changes in the amount, type, and timing of precipitation, increased evapotranspiration rates, and reduced aquifer recharge; and (2) reductions in springflow as a result of changes in human behavior in response to climate change (*e.g.,* increased groundwater pumping as surface water resources disappear). A reduction in springflow could be exacerbated by the greater severity of droughts being experienced in the southwestern United States, including Nevada (Snyder et al. 2019, pp. 2–4; Williams et al. 2020, pp. 1–5). Higher temperatures and drier conditions could result in greater evapotranspiration, leading to increased drying of wetland habitat. Impacts vary geographically and identifying the vulnerability of individual springs is challenging. For example, each spring studied in Arches National Park in Utah responded to local precipitation and recharge differently, despite similarities in topographic setting, aquifer type, and climate exposure (Weissinger 2016, p. 9).

Predicting individual spring response to climate change is further complicated by the minimal information available about the large hydrological connections for most sites and the high degree of uncertainty inherent in future precipitation models. Regardless, the best available data indicate that the Dixie Valley toad may be vulnerable to climate change, but the best available science currently does not allow for us to predict where and to what degree impacts may manifested.

Groundwater Pumping

The basin is fully appropriated for consumptive groundwater uses (18,758,663 cubic meters per year (m^3/yr) (15,218 acre-feet per year (afy)) of an estimated 18,489,943 m^3/yr (15,000 afy) perennial yield; NDWR 2021, entire), and the proposed Dixie Valley groundwater export project by Churchill County is seeking an additional 12,326,628–18,489,943 m^3/yr (10,000–15,000 afy) (Huntington et al. 2014, p. 2). Total geothermal water rights appropriated in Dixie Valley as of 2020 are 15,659,749 m^3/yr (12,704 afy) (BLM 2021b, pp. 2–28).

Increased groundwater pumping in Nevada is primarily driven by human water demand for municipal purposes; irrigation; and development for oil, gas, geothermal resources, and minerals. Many factors associated with groundwater pumping can affect whether or not an activity will impact a spring. These factors include the amount of groundwater pumped, period of pumping, the proximity of pumping to a spring, depth of pumping, and characteristics of the aquifer being impacted. Depending on these factors, groundwater withdrawal may result in no measurable impact to springs or may reduce spring discharge, change the temperature of the water, reduce free-flowing water, dry springs, alter Dixie Valley toad habitat size and heterogeneity, or create habitat that is more suited to nonnative species than to native species (Sada and Deacon 1994, p. 6). Pumping rates that exceed perennial yield can lower the water table, which in turn will likely affect riparian vegetation (Patten 2008, p. 399).

Determining when groundwater withdrawal exceeds perennial yield is difficult to ascertain and reverse due to inherent delays in detection of pumping impacts and the subsequent lag time required for recovery of discharge at a spring (Bredehoeft 2011, p. 808). Groundwater pumping initially captures stored groundwater near the pumping area until water levels decline and a

cone of depression expands, potentially impacting water sources to springs or streams (Dudley and Larson 1976, p. 38). Spring aquifer source and other aquifer characteristics influence the ability and rate at which a spring fills and may recover from groundwater pumping (Heath 1983, pp. 6, 14). Depending on aquifer characteristics and rates of pumping, recovery of the aquifer is variable and may take several years or even centuries (Heath 1983, p. 32; Halford and Jackson 2020, p. 70). Yet where reliable records exist, most springs fed by even the most extensive aquifers are affected by exploitation, and springflow reductions relate directly to quantities of groundwater removed (Dudley and Larson 1976, p. 51).

The most extreme potential effects of groundwater withdrawal on the Dixie Valley toad are likely desiccation and extirpation or extinction. If groundwater withdrawal occurs but does not cause a spring to dry, there can still be adverse effects to Dixie Valley toads or their habitat because reduction in springflow reduces both the amount of water and amount of occupied habitat. If the withdrawals also coincide with altered precipitation and temperature from climate change, even less water will be available. Cumulatively, these conditions could result in a delay in groundwater recharge at springs, which may then result in a greater effect to the Dixie Valley toad than the effects of the individual threats acting alone. Across the Dixie Meadows springs, discharge varies greatly, with some springs with low discharge at the current time likely due to a combination of influences, both natural and anthropogenic. Although there is much uncertainty around the magnitude and timing of groundwater withdrawal, and thus the possible effects on the Dixie Meadows spring system, we anticipate that the future effects of groundwater withdrawal could have significant effects on the Dixie Meadows spring system.

Current Condition

Redundancy, Representation, and Resiliency

Population estimates are not available for the Dixie Valley toad. Time-series data of toad abundance are available from various surveys conducted by the Service and the Nevada Department of Wildlife (NDOW) during the period 2009–2012 (before the Dixie Valley toad was recognized as a species); however, differences in sample methodology between years and low recapture rates of marked toads make it difficult to infer temporal trends or population size. In addition to adult toads, surveys recorded eggs, tadpoles, and juveniles in all survey years, suggesting consistent reproduction is occurring.

Adult toads currently have high occupancy rates and are generally more likely than not to occur across the Dixie Meadows wetlands (Rose et al. 2022, p. entire). Dixie Valley toad larvae were more likely detected areas with high surface water, low emergent vegetation, and water temperatures between 20–28 °C (68–82.4 °F) (Rose et al. 2022, entire).

Larvae are detected less often than adults and warmer water temperatures strongly influence the probability of reproduction (Halstead et al. 2019, pp. 10–11). This finding suggests that adult toads are seeking out a subset of habitat for reproduction based in part on water temperature. The percentage of the range currently occupied by adults remained similarly high throughout 2018–2022 and across seasons (Rose et al. 2022, entire). The high occupancy rate observed from 2018 through 2022, and evidence of reproduction observed in the period 2009–2022, indicate that the Dixie Valley toad is currently maintaining resilience to the historical and current environmental stochasticity present at Dixie Meadows (Rose et al. 2022, entire). However, the narrowly distributed, isolated nature of the single population of the species indicates that the Dixie Valley toad has little ability to withstand stochastic or catastrophic events through dispersal. Because the species evolved in a unique spring system with little historical variation, we conclude that it has low potential to adapt to environmental changes to its habitat. As a single-site endemic with no dispersal opportunities outside the current range, the species has inherently low redundancy and representation and depends entirely on the continued availability of habitat in Dixie Meadows.

Below, we discuss the potential impacts the Dixie Meadows Geothermal Utilization Project could have on both the current and future status of the Dixie Valley toad. Based on an expert knowledge elicitation (discussed further below) conducted on the potential outcomes of this geothermal project, peak change to the spring system could occur as early as year 1 of geothermal pumping, with a 90 percent chance that peak change will occur within 10 years of the start of geothermal pumping (Service 2022, pp. 42–43).

Dixie Meadows Geothermal Project

In addition to 50 active geothermal leases within Dixie Valley in Churchill County, two geothermal exploration projects were approved in Dixie Meadows in 2010 and 2011 (BLM 2010, entire; BLM 2011, entire). Most recently, on November 23, 2021, BLM approved and permitted the Dixie Meadows Geothermal Utilization Project (BLM 2021b, entire) after issuing two draft environmental assessments, receiving extensive comments from the Service and NDOW, and developing a Monitoring and Mitigation Plan. This project will consist of up to two 30–MW geothermal power plants on 6.5 ha (16 ac) each; up to 18 well pads (107×114 m (350×375 ft)), upon which up to three wells per pad may be drilled for exploration, production, or injection; pipelines to carry geothermal fluid between well fields and the power plant(s); and either a 120-kilovolt (kV) or a 230-kV transmission gen-tie and associated access roads and structures (BLM 2021b, p. 1–1). The project proponent (Ormat Nevada Inc. (Ormat)) began construction on the first geothermal plant the week of February 14, 2022, and plans to begin geothermal production by 2024 after completing 12 months of monitoring as described in the Monitoring and Mitigation Plan (BLM 2021b, appendix H). To see a more detailed overview of the approved and permitted project, refer to the BLM November final EA.

As mentioned above, two geothermal exploration projects were approved by the BLM in 2010 and 2011 (BLM 2010, entire; BLM 2011, entire); however, required monitoring and baseline environmental surveys for those exploration projects did not occur (BLM 2021a, pp. 3–17–3–18). As a result, key environmental information (*e.g.,* water quality metrics data such as flow, water temperature, and water pressure) is lacking to determine the effects of the projects on the surrounding environment. Most of the information collected during this timeframe consisted of singular measurements taken quarterly or annually, which do not characterize the variability in environmental conditions observed in Dixie Meadows. The lack of robust baseline environmental information is part of why we, along with experts from the expert knowledge elicitation workshop panel (described below), conclude that the November Monitoring and Mitigation Plan associated with the Dixie Meadows Geothermal Utilization Project needs further refinement to adequately detect and respond to changes in the wetlands and toad populations. The ability of the November Monitoring and Mitigation Plan to detect changes in baseline conditions, and mitigate those changes, is discussed below.

Expert Knowledge Elicitation

An expert knowledge elicitation workshop was carried out during the period August 17–20, 2021, using the then proposed Dixie Meadows Geothermal Utilization Project January draft EA and Monitoring and Mitigation Plan, along with a summary of all existing data, to determine the range of outcomes of the approved project. This workshop followed established best practices for eliciting expert knowledge (Gosling 2018, entire; O'Hagan 2019, pp. 73–81; Oakley and O'Hagan 2019, entire). The expert panel consisted of a multidisciplinary group with backgrounds in the geologic structure of basin and range systems, various components of deep and shallow groundwater flow, as well as geothermal exploration and development. All panelists have direct experience in the Great Basin, and most in Dixie Valley and Dixie Meadows, specifically. The panelists were asked questions regarding the time until peak changes to the spring system would occur, the ability of the January Monitoring and Mitigation Plan to detect and mitigate change, the amount of time it would take to mitigate change if mitigation is possible, and what the peak changes to springflow and spring temperature could be. For a detailed overview of the expert knowledge elicitation process, refer to the SSA report (Service 2022, appendix A).

The expert panelists concluded that the Dixie Meadows spring system will change quickly, and detrimentally, once geothermal energy production begins, with a median response time of roughly 4 years and a 90 percent chance that the largest magnitude changes will occur within 10 years (Service 2022, appendix A). Uncertainty within individual judgments on response time was related to the efficacy of mitigation measures and interactions between short-term impacts from geothermal development and longer-term impacts from climate change and consumptive water use.

Experts had low confidence in the ability of the January Monitoring and Mitigation Plan to both detect and mitigate changes to the temperature and flow of surface springs in Dixie Meadows. Although the aggregated distribution for the ability to detect changes ranged from 0 to 100 percent, the median expectation was a roughly 38 percent chance of detecting changes (Service 2022, appendix A). These judgments reflect an expectation that there is less than 50 percent confidence from the experts that the January Monitoring and Mitigation Plan could detect changes in the spring system due to the complexity and natural variability of the system, limited baseline data, and perceived inadequacies of the January Monitoring and Mitigation Plan. The January Monitoring and Mitigation Plan was perceived as inadequate due in part to limited monitoring locations, low frequency of monitoring and reporting, and lack of a statistical approach for addressing variability and uncertainty. The degree of confidence in the ability to mitigate environmental impacts of the project was even lower (median of roughly 29 percent; Service 2022, appendix A) based on previously stated concerns about the plan, lack of information on how water quality would be addressed, interacting effects of climate change and extractive water use, and questions about the motivation to mitigate if measures ran counter to other operating goals of the plant.

The expert panel was asked what timeframe would be required to fully mitigate changes in spring temperature and springflow once detected—assuming that changes have been detected, it is technically feasible to mitigate the problem, and there is a willingness to participate from all parties. Based on those assumptions, the experts judged that it could take multiple years to mitigate perturbations once detected, with a median expectation of 4 years (Service 2022, appendix A).

At the time the expert knowledge elicitation occurred, the Dixie Meadows Geothermal Utilization Project was not approved. However, in the discussion about expected peak change in spring temperature and springflow, the experts considered how the spring system would change if the geothermal project was not approved or the January Monitoring and Mitigation Plan was improved. Expert judgments on expected peak change in spring temperature and springflow that considered the geothermal project not getting approved and an improvement in the January Monitoring and Mitigation Plan were not considered in our analysis because the geothermal project was approved in November 2021. Additionally, although the November Monitoring and Mitigation Plan included significant revisions to the frequency of monitoring, those revisions did not substantially affect the ability of the plan to detect or mitigate changes in the spring system. Therefore, it is unlikely the results of the expert knowledge elicitation completed on the January draft EA and the then-existing Monitoring and Mitigation Plan would have changed meaningfully in response to the November final approved EA and Monitoring and Mitigation Plan.

Although there is considerable uncertainty in the magnitude of expected changes from the approved project, there is a high degree of certainty that geothermal energy development will have severe and negative effects on the geothermal springs relied upon by the Dixie Valley toad, including reductions in spring temperature and springflow, which directly affect the resource needs of the species. The plausible range of changes to spring temperatures ranged from a decrease of 10 °C (18 °F) to 55 °C (99 °F) (Service 2022, appendix A). This range is due to the wide spatial variation in spring temperatures across the spring system and reflects the expectation that the spring temperatures could plausibly drop to ambient levels (*i.e.,* a complete loss of geothermal contributions). Similarly, the experts considered it plausible that springs in Dixie Meadows could dry up (no surface discharge) as the geothermal contribution was reduced, with up to a 31 percent decrease in surface discharge. These judgments reflect the range of operations that may be implemented under the phased power plant approach, perceived inadequacies with the January Monitoring and Mitigation Plan, and the fact that drying of surface springs has been documented at other nearby geothermal development projects (BLM 2022, p. 1) indicates this may be a plausible outcome.

Scenario Considerations for Current and Future Conditions

In the SSA report, we analyzed four scenarios based on the expert knowledge elicitation. As mentioned earlier, these scenarios could plausibly affect both the current and future condition of the species. Three of the scenarios (scenarios 1–3) assume the Dixie Meadows Geothermal Utilization Project will begin construction as approved, while scenario 4 assumes there will be no geothermal development or the November Monitoring and Mitigation Plan will be significantly improved before project implementation. Scenario 4 was not considered in this decision given the approval of the geothermal project, the beginning of construction on the project, and the lack of substantive improvements to the November Monitoring and Mitigation Plan. As discussed above under ''Expert Knowledge Elicitation,'' we have low confidence in the ability of the November Monitoring and Mitigation Plan to detect or mitigate changes to the spring system, or to adequately mitigate for potential effects from the project.

Therefore, only scenarios 1–3 were considered for this decision.

The scenarios incorporated the following considerations from the expert knowledge elicitation: the efficacy of the November Monitoring and Mitigation Plan; how the surficial spring system will respond to geothermal production; and changes in temperature, evapotranspiration, and extreme precipitation events related to climate change. For all scenarios, we project that the basin will remain over-allocated. The lower bound of scenarios (scenario 1) projects that the November Monitoring and Mitigation Plan is ineffective; the springs dry completely; and there are increases in air temperature, evapotranspiration, and extreme precipitation events seen under RCP 8.5. This scenario represents the low confidence the experts have in the November Monitoring and Mitigation Plan and reflects the results in a similar situation that occurred in Jersey Valley where geothermal production caused the spring system to go dry within 3 years of the start of operation (BLM 2022, p. 1; NDWR 2022, unpublished data). The upper bound of scenarios (scenario 3) projects that the November Monitoring and Mitigation Plan is moderately effective; geothermal production has moderate effects on the surficial spring system; and increases in temperature, evapotranspiration, and moderate changes in precipitation seen under RCP 4.5 occur. Because the experts expressed less than 50 percent confidence in the ability of the November Monitoring and Mitigation Plan to both detect and mitigate change, it was logical for this scenario to represent the upper bound of plausibility. Put another way, the experts did not consider it likely that geothermal production would have minor or negligible effects on the surface spring system.

These scenarios include the range of peak changes to spring temperature and springflow as discussed earlier (a decrease of 10 °C (18 °F) to 55 °C (99 °F) in spring temperature, and a 31–100 percent decrease in springflow). These projected changes in spring temperature and flow were used as inputs into a multistate, dynamic occupancy model, which is described further in the SSA report (Service 2022, pp. 61–64). Scenario 1 results in complete reproductive failure because of the drying of springs, and scenarios 2 and 3 project a risk of reproductive failure after 1 year of geothermal production. Under scenario 2, the mean percentage of the range occupied by larvae drops to 0 percent by year 4 of geothermal production. Scenario 3 projects a mean of 1 percent of the range occupied by larvae by year 6 of geothermal production. All scenarios result in a high level of risk of reproductive failure for the Dixie Valley toad in the near future.

Although the occupancy model described above represents the best available projection framework for the Dixie Valley toad, not all demographic and risk factors relevant to understanding species viability are included. One major threat not accounted for by the model is the synergistic effect of changes in temperature with the risk posed by exposure to the fungal pathogen chytrid fungus that causes the disease chytridiomycosis (see ''Disease,'' above). Chytrid fungus growth and survival are sensitive to both cold and hot temperatures, with optimal growth conditions in culture occurring between 15 and 25 °C (59 and 77 °F). There is equivocal evidence on whether colder temperatures limit the effects of chytrid fungus (Voyles et al. 2017, pp. 367–369); however, hot geothermal waters above 25 °C (77 °F) appear to provide protection against chytrid fungus by allowing individuals to raise body temperatures through behavioral fever (Forrest and Schlaepfer 2011, entire; Murphy et al. 2011, p. 39). This information indicates that future decreases in water temperature associated with scenarios 2 and 3 are likely to increase the risk that chytrid fungus could become established within the Dixie Valley toad population. If chytrid fungus becomes established within the Dixie Valley toad population, there would be negative, and plausibly catastrophic, effects to the species.

The seasonal timing of changes in water temperature is also particularly important. Dixie Valley toads strongly rely on aquatic environments throughout their life cycle (Halstead et al. 2021, entire). Unlike western toads that may be found hundreds to thousands of meters from aquatic breeding sites, in surveys, Dixie Valley toads are almost always found in water (Halstead et al. 2021, pp. 30–31). When not detected in water, Dixie Valley toads are found 4.2 m (13.8 ft) from water on average and are found both in and above water during brumation (Halstead et al. 2021, p. 30). Toads select autumn brumation sites that are warmer than random locations available, and toads are 1.3 times more likely to select sites for each 1 °C (1.8 °F) increase in water temperature (Halstead et al. 2021, p. 30). Because toads are found closer to spring heads in autumn compared to sites selected during other times of year, it is likely that they are selecting areas where water temperatures will remain stable throughout the winter (Halstead et al. 2021, p. 34). The selection of areas with stable, warm water temperatures indicates that reductions in geothermal contributions during winter could lead to thermal stress, reductions in available habitat as waters cool, or even mortality if geothermal contributions are removed completely or reduced to a level that toads are unable to adapt their brumation strategies.

Conservation Efforts and Regulatory Mechanisms

The Dixie Valley toad occurs only on Federal lands (the DoD's Fallon Naval Air Station and BLM). Various laws, regulations, policies, and management plans may provide conservation or protections for Dixie Valley toads. As such, the following management plans are the existing conservation tools driving the management of Dixie Valley toads and their habitat:

- As required by the Sikes Act (16 U.S.C. 670 *et seq.,* as amended), the DoD has an integrated natural resources management plan (INRMP) (AMEC Environmental and Infrastructure, Inc., 2014, entire) in place for supporting both the installation mission as well as protecting and enhancing installation resources for multiple use, sustainable yield, and biological integrity. The INRMP is being updated to incorporate the DoD's National Strategic Plan for amphibian and reptile conservation and management (Lovich et al. 2015, entire), which will include specific management for Dixie Meadows and the Dixie Valley toad.
- As required by the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), BLM has a resource management plan for all actions and authorizations involving BLM-administered lands and resources.

In compliance with the National Environmental Policy Act of 1970, as amended (42 U.S.C. 4321 *et seq.*), which is a procedural statute, for projects that Federal agencies fund, authorize, or carry out, BLM, with input from Ormat, developed a Monitoring and Mitigation Plan for the Dixie Meadows Geothermal Utilization Project; it is an appendix in BLM's November final EA. The goal of the November Monitoring and Mitigation Plan is to identify hydrologic and biologic resources, spring-dependent ecosystems, aquatic habitat, and species that could be affected by geothermal exploration, production, and injection in the Dixie Meadows area. The November Monitoring and Mitigation Plan will describe the plan Ormat will implement to monitor and mitigate potential effects to those

resources, ecosystems, habitat, and species.

The November Monitoring and Mitigation Plan includes adaptive management and mitigation measures that Ormat would implement if changes are detected in baseline conditions and threshold values are exceeded. Management actions may include geothermal reservoir pumping and injection adjustments (*e.g.,* redistribution of injection between shallow and deep aquifers). Other more aggressive actions include augmenting affected springs with geothermal fluids or fresh water to restore preproduction temperature, flow, stage, and water chemistry. The November Monitoring and Mitigation Plan states that if mitigation actions are not sufficient for the protection of species and aquatic habitat, pumping and injection would be suspended until appropriate mitigation measures are identified, implemented, and shown to be effective.

We, along with other interested parties (*e.g.,* Department of the Navy, NDOW) provided comments to the BLM regarding the November Monitoring and Mitigation Plan, which was first made available to the public in January 2021. We have low confidence in the ability of the November Monitoring and Mitigation Plan to adequately detect and respond to changes because of the complexity and natural variability of the spring system, limited baseline data, and perceived inadequacies of the plan. We determined the November Monitoring and Mitigation Plan is inadequate because of the inadequate time to collect relevant baseline information prior to beginning operation of the plant, limited monitoring locations, lack of a statistical approach for addressing variability and uncertainty, lack of information on how water quality would be addressed, interacting effects of climate change and extractive water use, and uncertainty about the feasibility of certain mitigation measures and implementation of mitigation if measures ran counter to other operating goals of the plant.

The changes made between the January 2021 and November 2021 versions of the Monitoring and Mitigation Plan did not change our view that the plan is inadequate to detect potential changes to the spring system or mitigate for potential effects from project operations. We address the changes made between the two versions under *Public Comments,* above (see, in particular, Comments 24, 25, 26, 40, and 42). The issues mentioned in the previous paragraph remain; therefore, our conclusion that the plan in its current form is not sufficient to protect the Dixie Valley toad and its habitat remain the same.

- Nevada Administrative Code (NAC) at section 503.075(2)(b) lists the Dixie Valley toad as a protected amphibian in the State of Nevada. Under the NAC at section 503.093(1), there is no open season on those species of amphibian classified as protected by the State: ''[e]xcept as otherwise provided . . . , a person shall not hunt or take any wildlife which is classified as protected, or possess any part thereof, without first obtaining the appropriate license, permit or written authorization from the [NDOW].'' Under the NAC at section 503.0935, the State may issue a special permit to allow a person to handle, move, or temporarily possess any wildlife which is classified as protected for the purpose of reducing or eliminating the risk of harm to the wildlife that may result from any lawful activity conducted on land where the wildlife is located. Under the NAC at section 503.094, the State issues permits for the take and possession of any species (including protected species) of wildlife only for scientific or educational purposes.

The Nevada Department of Conservation and Natural Resources includes the Nevada Division of Natural Heritage (NDNH), which tracks the species status of plants and animals in Nevada. The NDNH recognizes Dixie Valley toads as critically imperiled, rank *S1*. Ranks of *S1* are defined as species with very high risks of extirpation in the jurisdiction due to very restricted range, very few populations or occurrences, very steep declines, severe threats, or other factors.

Determination of Dixie Valley Toad's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of endangered species or threatened species. The Act defines an ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range and a ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

In conducting our status assessment of the Dixie Valley toad, we evaluated all identified threats under the Act's section 4(a)(1) factors and assessed how the cumulative impact of all threats acts on the viability of the species as a whole. That is, all the anticipated effects from both habitat-based and direct mortality-based threats are examined in total and then evaluated in the context of what those combined negative effects will mean to the future condition of the Dixie Valley toad.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we determined that the Dixie Valley toad is currently at risk of extinction throughout its range primarily due to the approval and commencement of geothermal development (Factor A). Other threats identified in this status determination include increased severity of drought due to climate change (Factor A); the threat of chytrid fungus establishing itself in the population (Factor C); groundwater pumping associated with human consumption, agriculture, and county planning (Factor A); and predation by invasive bullfrogs (Factor C). These other threats will likely exacerbate the main threat of geothermal development. Existing regulatory mechanisms do not address the primary threat to the species (Factor D).

Construction of the Dixie Meadows Geothermal Utilization Project has begun, and the first phase of geothermal production is planned to begin before the end of 2024. Based upon the best available scientific and commercial information as described in this determination, the Service has a high degree of certainty that geothermal production will have severe, negative effects on the geothermal springs the species relies upon for habitat (Factor A). These negative effects include reductions in spring temperature and springflow, which directly affect the needs of the species (*i.e.,* adequate water temperature, sufficient wetted areas, sufficient wetland vegetation, including vegetation cover, and adequate water quality (see *Species Needs,* above)). The best available information indicates that a complete reduction in springflow and significant reduction of water temperature are plausible outcomes of the geothermal project, and these conditions could result in the species no

longer persisting (*i.e.,* becoming extinct or functionally extinct as a result of significant habitat degradation, or no reproduction due to highly isolated, non-recruiting individuals).

The narrowly distributed, isolated nature of the single, small population of the species indicates that the Dixie Valley toad will have no ability to withstand stochastic or catastrophic events through dispersal. Because the species occurs in only one spring system and has not experienced habitat changes of the magnitude or pace projected, it may have low potential to adapt to a fast-changing environment. As a single-site endemic with no dispersal opportunities outside the current range and low adaptive capacity, the species has inherently low redundancy and representation, and depends entirely on the continued availability of wetland habitat in Dixie Meadows. Low redundancy and representation make the Dixie Valley toad particularly vulnerable to fast-paced change to its habitat and catastrophic events, any of which could plausibly result from the permitted Dixie Meadows Geothermal Utilization Project.

The Dixie Valley toad exists in one population that will likely be directly affected to a significant degree by geothermal production in a short timeframe, resulting in a high risk that the species could become extinct.

In addition to the current development of the geothermal project, a combination of threats will act synergistically to exacerbate effects from geothermal production on the Dixie Meadows spring system. A reduction in springflow could be exacerbated by the greater severity of droughts being experienced in the southwestern United States, including Nevada (Snyder et al. 2019, pp. 2–4; Williams et al. 2020, pp. 1–5). Higher temperatures and drier conditions could result in greater evapotranspiration, leading to increased drying of wetland habitat. A reduction in water temperature could allow chytrid fungus to become established and negatively impact the Dixie Valley toad population. Chytrid fungus would likely be catastrophic to Dixie Valley toads, as it has caused severe declines in other amphibian species, and the fungus has been found in another known vector species (bullfrog) in Turley Pond, which is about 10 km (6.2 mi) from the southern range of the Dixie Valley toad (Forrest 2013, p. 77). Bullfrogs themselves are a threat to the species, as Dixie Valley toads could be easily preyed upon because of their small size. If bullfrogs were to become established throughout the Dixie Valley toad's habitat, there would likely be a reduction in Dixie Valley toad abundance.

Thus, after assessing the best available information, we conclude that the Dixie Valley toad is currently in danger of extinction throughout all of its range due to the immediacy of the threat of geothermal production, including negative effects such as reductions in spring temperature and springflow, which would directly affect the needs of the species (*i.e.,* adequate water temperature, sufficient wetted areas, sufficient wetland vegetation, including vegetation cover, and adequate water quality), and low confidence in the ability of the Mitigation and Monitoring Plan to effectively minimize and mitigate for potential effects that are likely to manifest in the near term. We find that threatened species status is not appropriate because the threat of extinction is imminent as opposed to being likely to develop within the foreseeable future.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We have determined that the Dixie Valley toad is in danger of extinction throughout all of its range and, accordingly, did not undertake an analysis of any significant portion of its range. Because the Dixie Valley toad warrants listing as endangered throughout all of its range, our determination does not conflict with the decision in *Center for Biological Diversity* v. *Everson,* 435 F. Supp. 3d 69 (D.D.C. 2020), because that decision related to significant-portion-of-the-range analyses for species that warrant listing as threatened, not endangered, throughout all of their range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Dixie Valley toad meets the Act's definition of an endangered species. Therefore, we are listing the Dixie Valley toad as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species remains endangered or may be reclassified from endangered to threatened (''downlisted'') or removed from protected status (''delisted'') and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*https://www.fws.gov/program/endangered-species*) (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a

broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this final rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Nevada will be eligible for Federal funds to implement management actions that promote the protection or recovery of the Dixie Valley toad. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/service/financial-assistance*.

Please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph may include, but are not limited to:

- Management planning and permitting on Federal lands, such as fire management plans, mining permits, integrated natural resources management plans, land resource management plans, oil and natural gas permits, and geothermal project approvals; and
- Landscape-altering activities on Federal lands, such as aquatic habitat restoration, fire suppression, fuel reduction treatments, renewable energy development, renewable and alternative energy projects, and geothermal project implementation.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any species listed as an endangered species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Vehicle use on existing roads and trails in compliance with the BLM Carson City District's resource management plan.

(2) Recreational use with minimal ground disturbance (*e.g.,* hiking, walking).

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act if they are not authorized in accordance with applicable law, including the Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species;

(2) Unauthorized livestock grazing that results in direct mortality and direct or indirect destruction of vegetation and aquatic habitat;

(3) Destruction/alteration of the species' habitat by draining, ditching, stream channelization or diversion, or diversion or alteration of surface or ground water flow into or out of the wetland;

(4) Introduction of nonnative species that compete with or prey upon the Dixie Valley toad or wetland vegetation;

(5) The unauthorized release of biological control agents that attack any life stage of the Dixie Valley toad;

(6) Modification of the vegetation components on sites known to be occupied by the Dixie Valley toad; and

(7) Modification of spring and wetland water temperatures.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Reno Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act for endangered species or the 4(d) rule (for threatened species). Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than

negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed in the SSA report, there is currently no imminent threat of collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA report and the emergency listing rule for the Dixie Valley toad (87 FR 20336; April 7, 2022), we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to Dixie Valley toad and that those threats in some way can be addressed by the Act's section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because the Secretary has not identified other circumstances for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the Dixie Valley toad.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the Dixie Valley toad is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. Careful assessments of the economic impacts that may occur due to a critical habitat designation are not yet complete. Therefore, data sufficient to perform required analyses are lacking, and we conclude that the designation of critical habitat for the Dixie Valley toad is not determinable at this time. The Act allows the Service an additional year to publish a critical habitat designation that is not determinable at the time of listing (16 U.S.C. 1533(b)(6)(C)(ii)).

Administrative Procedure Act

The April 7, 2022, emergency rule (87 FR 20336) that implemented temporary (240-day) protections for the Dixie Valley toad expires on December 2, 2022. Given the immediate threat geothermal development poses to the species, we conclude that it is necessary to establish immediate and seamless protection under the Act for the Dixie Valley toad. Therefore, we have determined that, under the exemption provided in the Administrative Procedure Act (5 U.S.C. 553(d)(3)), ''good cause'' exists to make these regulations effective upon publication (see **DATES**, above).

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We requested information from the Paiute-Shoshone Tribe of the Fallon Reservation and Colony during the SSA process. We received a request for a government-to-government consultation from the Paiute-Shoshone Tribe of the Fallon Reservation and Colony during the public comment period and are working toward initiating conversations with the tribe. We will continue to work with Tribal entities in the future, including during development of a critical habitat designation for the Dixie Valley toad.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Reno Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, amend paragraph (h) by adding an entry for ''Toad, Dixie Valley'' to the List of Endangered and Threatened Wildlife in alphabetical order under AMPHIBIANS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	* * *
Amphibians				
*	*	*	*	* * *
Toad, Dixie Valley	*Anaxyrus williamsi*	Wherever found	E	87 FR [Insert FEDERAL REGISTER page where the document begins], 12/2/2022.
*	*	*	*	* * *

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–26237 Filed 12–1–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2019–0070; FXES11130900000C2–189–FF09E42000]

RIN 1018–BD01

Endangered and Threatened Wildlife and Plants; Reclassification of Eugenia woodburyana From Endangered to Threatened With a Section 4(d) Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are reclassifying (downlisting) the plant *Eugenia woodburyana* (no common name) from an endangered species to a threatened species under the Endangered Species Act of 1973, as amended (Act), due to improvements in the species' status since its original listing in 1994. This action is based on a thorough review of the best available scientific and commercial information, which indicates that *E. woodburyana* is not currently in danger of extinction throughout all or a significant portion of its range, but it is likely to become so within the foreseeable future. We are also finalizing a rule issued under section 4(d) of the Act to provide measures that are necessary and advisable for the conservation of *E. woodburyana.*

DATES: This rule is effective January 3, 2023.

ADDRESSES: The supporting documents we used in preparing this rule and public comments we received on the proposed rule are available on the internet at *https://www.regulations.gov* in Docket No. FWS–R4–ES–2019–0070.

FOR FURTHER INFORMATION CONTACT: Edwin Muñiz, Field Supervisor, Caribbean Ecological Services Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boqueron, PR 00622; email *caribbean_es@fws.gov;* telephone 787–405–3641. 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:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to no longer be an endangered or threatened species, we may reclassify the species or remove it from the Federal Lists of Endangered and Threatened Wildlife and Plants due to recovery. A species is an ''endangered species'' for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range and is a ''threatened species'' if it is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. We are reclassifying *Eugenia woodburyana* from endangered to threatened (*i.e.,* ''downlisting'' the species) because we have determined that the species is no longer in danger of extinction throughout all or a significant portion of its range. Downlisting a species can only be completed by issuing a rule.

What this document does. This rule reclassifies *E. woodburyana* from endangered to threatened (*i.e.,* ''downlists'' the species), with a rule issued under section 4(d) of the Act, based on the species' current status, which has been improved through implementation of conservation actions.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any one or a combination of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. In our May 2017, 5-year status review, we made a recommendation to reclassify this plant from endangered to threatened based on our evaluation of these same five factors. Based on the status review, the current threats analysis, and evaluation of conservation measures, we conclude that the plant *E. woodburyana* no longer meets the Act's definition of an endangered species, and we are reclassifying it as a threatened species because it is no longer in danger of extinction throughout all or a significant portion of its range but is likely to become so within the foreseeable future.

New information indicates that *E. woodburyana* is now more abundant and more widely distributed than when it was listed in 1994, when only approximately 45 individuals were known from 3 localities in southwestern Puerto Rico. In the recovery plan for *E. woodburyana* (Service 1998), the species was identified as occurring in 4 locations in southwest Puerto Rico, totaling approximately 150 individuals. Currently, self-sustaining *E. woodburyana* natural populations are known to occur in 6 localities along southern Puerto Rico, extending from the municipality of Cabo Rojo in the southwest eastward to the municipality of Salinas in the south, totaling approximately 2,751 individuals, not including seedlings. About 47 percent of the currently known individuals occur under protective status in areas managed for conservation and where threats due to habitat modification have been reduced. Recovery actions (*e.g.,*

propagation and planting, habitat enhancement with native tree species, cattle exclusion, firebreaks) to control and reduce remaining threats have been successfully implemented in collaboration with several partners.

Our review of the best available scientific and commercial information indicates that some threats to *E. woodburyana* still remain while others have been reduced. Remaining threats that will make this species likely to become endangered in the foreseeable future include habitat loss, degradation, and fragmentation, and other natural or manmade factors such as human-induced fires and landslides.

We are promulgating a section 4(d) rule. We are specifically tailoring the incidental take exceptions under section 9(a)(1) of the Act to the species to provide protective mechanisms to State and Federal partners so that they may continue with certain activities that are not anticipated to cause direct injury or mortality to *E. woodburyana* and that will facilitate the conservation and recovery of the species.

Peer review and public comment. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we solicited expert opinion on our October 21, 2020, proposed rule to downlist *E. woodburyana* (85 FR 66906). The Service sent the proposed rule to five independent peer reviewers and received three responses. The purpose of peer review is to ensure that our determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise that includes familiarity with the species and its habitat, biological needs, and threats.

Previous Federal Actions

This species was originally listed as endangered under the Endangered Species Act on September 9, 1994 (59 FR 46715). On October 21, 2020, we proposed to downlist *E. woodburyana* from endangered to threatened (85 FR 66906). Please refer to that proposed rule for a detailed description of previous Federal actions concerning this species. The proposed rule and supplemental documents are provided at *https://www.regulations.gov* under Docket No. FWS–R4–ES–2019–0070.

Summary of Changes From the Proposed Rule

In preparing this final rule, we reviewed and fully considered all comments we received during the comment period from the peer reviewers and the public on the proposed rule to downlist *E. woodburyana.* We made minor changes and corrections throughout this document in response to comments. However, the information we received during the public comment period on the proposed rule did not change our determination that *E. woodburyana* should be reclassified from endangered to threatened under the Act.

Summary of Comments and Recommendations

In the proposed rule published on October 21, 2020 (85 FR 66906), we requested that all interested parties submit written comments on the proposal by December 21, 2020. We also contacted the Puerto Rico Department of Natural and Environmental Resources (PRDNER), scientific experts and organizations, and other interested parties and invited them to comment on the proposal. A newspaper notice inviting public to provide comments was published in Primera Hora on October 22, 2020.

On April 26, 2021, we reopened the comment period on the October 21, 2020, proposed rule for an additional 30 days and announced a public hearing on the proposed rule (86 FR 22005). A newspaper notice inviting public to provide comments at the public hearing was published in Primera Hora and El Nuevo Día on April 28, 2021, and at The Virgin Islands Daily News on April 27, 2021. We conducted the public hearing on May 12, 2021. No comments were received during or following the public hearing.

During the open comment periods, we received very few public comments, both in support of and opposed to our proposed downlisting of *Eugenia woodburyana,* but most did not include substantive information. Submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.'' All substantive information we received from the peer reviewers and from the public during the proposed rule's comment periods has either been incorporated directly into this final determination or is addressed below.

Peer Reviewer Comments

We reviewed all comments we received from peer reviewers for substantive issues and new information regarding *E. woodburyana.* The reviewers provided editorial and technical comments that were generally supportive of our approach; the peer reviewers made suggestions and comments that strengthened our analysis and improved the final rule.

(1) Comment: One peer reviewer stated that the Service cannot claim an increase in the number of *E. woodburyana* populations, as the historic population at Peñones de Melones was extirpated.

Response: We consider the geographical area of Peñones de Melones as a range extension of Sierra Bermeja, and, therefore, we do not consider the loss of the Peñones de Melones individuals as the extirpation of a genetically unique population critical for the recovery of the species. Moreover, the number of individuals recorded at Sierra Bermeja has steadily increased since the time of listing, evidence exists of reproductive events (flowers and fruit production) on a yearly basis, and the population structure shows multiple age classes, which indicates the population is improving.

(2) Comment: A peer reviewer stated that the population size of *E. woodburyana* is not sufficiently robust to reclassify the species to a threatened status. The reviewer highlights that a good population of any species must have at least 2,500 adult individuals to be considered a healthy population and that this is not the case for *E. woodburyana.* The peer reviewer asserts that existing *E. woodburyana* populations will continue decreasing due to ongoing threats.

Response: We have no information (either in our files or provided by commenters or reviewers) to indicate that 2,500 individuals is the minimum required to be a healthy population for this species, although we note that we presently have 2,751 individuals. As previously stated, the presence of different size classes in three (*i.e.,* Sierra Bermeja, Almácigo Bajo, and Cañon Murciélagos (GCF)) out of the six known *E. woodburyana* populations is an indicator of their improving status, and resilience to past and ongoing threats, but is not sufficient to demonstrate that the species has fully recovered as we have no evidence of the species naturally colonizing suitable habitat in the proximity of known populations.

Under the Act and our implementing regulations, a species may warrant

listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range (*i.e.,* if it meets the Act's definitions of an ''endangered species'' or a ''threatened species''). We make determinations of whether any species is an endangered species or a threatened species because of any of the five listing factors in section 4(a)(1) of the Act and based solely on the best scientific and commercial data available. As discussed below under Determination of *Eugenia woodburyana*'s Status, we have determined that *E. woodburyana* no longer meets the definition of an endangered species under the Act, but the species does meet the definition of a threatened species.

Public Comments

(3) Comment: One commenter questioned the implementation of several delisting criteria, including: (a) ''reduction and management of threats,'' (b) ''existing natural populations demonstrate a stable or increasing trend,'' and (c) ''establishment of three new populations of the species.'' The commenter explained that the issues affecting *E. woodburyana* recruitment will only worsen in the coming years as a result of climate change, the species' heavy reliance on rainfall for fruiting, and the potential for increased fire prevalence due to decreasing precipitation. Further, the commenter stated that the existence of multiple age classes of *E. woodburyana* at Finca Maria Luisa is not sufficient to indicate that the population is stable or increasing, as conservation recommendations have not been enforced and there is limited data on the sustainability or stability of the population. Finally, the commenter noted that survival following the first years after planting does not accurately reflect the long-term survival (viability) of the plant material. The commenter highlighted that the initial assessment of the planting efforts at La Tinaja in 2016 was promising, with an 87 percent survival rate, but decreased to 70 percent when it was reassessed in 2017, and then further to 45 percent when it was assessed in 2019.

Response: We acknowledge that recovery criteria for *E. woodburyana* have only been partially met, and the species will continue to have the protections of the Act as a threatened species. Additionally, recovery is a dynamic process that may or may not follow the criteria in a recovery plan due to a variety of factors (see Recovery, below). As stated above, we make our status determinations based on the best available scientific and commercial data at the time the determination is made. Our analysis of the best commercial and scientific information available indicates that *E. woodburyana* does not meet the Act's definition of an endangered species.

At present, we know of approximately 2,751 plants, which is an increase from the 45 individuals known at the time of listing. In addition, about 47 percent of the currently known *E. woodburyana* individuals occur within lands managed for conservation where habitat management practices are being implemented (*e.g.,* reforestation, cattle exclusion, and firebreaks). Although we acknowledge climate change scenarios will result in drier conditions within the subtropical dry forest life zone, its direct impacts on this species in the long term is uncertain because our ability to predict stressors associated with climate change is reduced beyond mid-century. At present, we have evidence of different size classes in three out of the six known populations (*i.e.,* Sierra Bermeja, Almácigo Bajo, and GCF), suggesting stability and persistence despite past on ongoing threats. In addition, we have not identified a decline in the number of known individuals in these three populations; in fact, the number of known plants has increased since the time of listing and evidence exists of ongoing reproductive events (flower and fruit production), indicating that these populations are in good health and stable.

In addition, available literature indicates that survival for existing plant reintroduction efforts is approximately 52 percent, and at least some sites are showing evidence of flower and fruit production, which are important characteristics of success for reintroduction efforts (Godefroid et al. 2011, p. 672). Planting and monitoring of individuals will continue to secure the long-term viability of ongoing efforts, and we will continue to work with our partners to secure the long-term viability and conservation of the species.

I. Reclassification Determination

Background

A thorough review of the taxonomy, life history, ecology, and overall viability of *E. woodburyana* was presented in the 5-year review (USFWS 2017, entire). Below, we present a summary of the biological and distributional information discussed in the 5-year review and new information published or obtained since.

Taxonomy and Species Description

Eugenia woodburyana is a small evergreen tree that belongs to the family Myrtaceae (Judd et al. 2002, p. 398). *Eugenia* is the largest genus of this family, which is very diverse in the Antilles and includes more native trees than any other genus of flowering plants in the flora of Puerto Rico (Breckon and Kolterman 1994, p. 5). *E. woodburyana* was first collected by Roy O. Woodbury in October 31, 1977, in the municipality of Guánica, Puerto Rico, and later described as a new species (Liogier 1994, p. 407). The species remains a valid species, and a recent molecular phylogenetic reconstruction to assess the evolutionary relationships of the Myrtaceae in the Caribbean confirmed its systematic placement within the genus *Eugenia* (Flickinger et al. 2020, p. 448).

Eugenia woodburyana may reach up to 6 meters (m) (19.8 feet (ft)) (Liogier 1994, p. 407). Its leaves are chartaceous (thin and stiff), pubescent on both sides, obovate or elliptic, rounded at the apex, and dark green and shiny above, and paler beneath. The fruit is an eight-winged, globose berry with a diameter of 2 centimeters (cm) (0.8 inches (in)) that turns red when mature (Liogier 1994, p. 407).

Reproductive Biology

The reproductive biology of *E. woodburyana* had not been thoroughly studied at the time it was listed. According to data in the recovery plan, herbarium specimens collected in October and May at the GCF contained buds and flowers, whereas specimens collected in February and April were sterile. However, a specimen collected in March in Sierra Bermeja (southwest Puerto Rico) had remnants of flowers (USFWS 1998, pp. 3–4).

Some information on the phenology and germination of *E. woodburyana* has been gathered since the species was listed. This plant has been observed flowering in February, May, June, August, and October, and not all individuals flower at the same time and not all produce fruits (USFWS 2017, p. 17). Therefore, we suspect it could flower February through October, depending on rain levels. Flower bud development has been observed 3 to 5 days after rain events of greater than 1 inch (25.4 millimeters (mm)) in 1 day, and fruits are observed about 3 weeks later (USFWS 2017, p. 17). In the event water availability becomes a limiting factor, the immature fruits may become dormant for months until conditions are favorable for developing (Monsegur-Rivera 2012–2017, pers. obs.). Flowers

of *E. woodburyana* are typically visited by honeybees (*Apis mellifera*), and pollination and fruit production appear to be the result of cross-pollination, as few fruits are produced when single individuals flower (Monsegur-Rivera 2012–2017, per. obs.).

Eugenia woodburyana seeds can remain dormant for a considerable period of time, and likely vary in time of emergence (Santiago 2011, p. 14). Recent germination trials indicate the species has a high germination rate (*i.e.,* 70 percent), and that germination success is greater if seeds are planted within 2 weeks following harvesting. Seeds start germinating by developing a long taproot, an adaptation to secure access to water, and in the case of a sudden drought, the seed may stop development of new growths and go dormant (Monsegur-Rivera 2012–2014, pers. obs.). *E. woodburyana* is relatively easy to propagate. Over the past 10 years, the Service has worked with local partners to propagate and plant this species on lands managed for conservation in the Sierra Bermeja area (USFWS 2017, p. 11).

Distribution and Abundance

Eugenia woodburyana was originally known from dry thickets within the GCF (Liogier 1980, p. 185; Breckon and Kolterman 1994, p. 5). In 1981, this species was collected within the Cabo Rojo National Wildlife Refuge (CRNWR), and in 1984, at the dry serpentine slopes of Cerro Mariquita in Sierra Bermeja (Santiago-Blay et al. 2003, p. 1). At the time of listing, *E. woodburyana* was considered an endemic species of southwest Puerto Rico, known from only 45 individuals within the GCF, Sierra Bermeja, and an individual reported from the CRNWR. In addition, *E. woodburyana* was collected in 1996, at Peñones de Melones in Cabo Rojo (Breckon 4863; MAPR herbaria). Thirteen individuals of this species were recorded during a study at La Tinaja Tract (Laguna Cartagena National Wildlife Refuge (LCNWR)), which found the species was present in open forest on east-facing slopes, and that it did not occur in areas in transition from pasture to forest (Weaver and Chinea 2003, p. 279).

Following the finalization of the species' recovery plan in 1998, new populations within the geographical areas of Montes de Barinas, between the municipalities of Yauco and Guayanilla, and Punta Cucharas, and between the municipalities of Ponce and Peñuelas, were identified by local experts and the Service (Román-Guzmán 2006, p. 25). These reports expanded the species' distribution farther east within the subtropical dry limestone forest of Puerto Rico. The known range of the species continued to expand: In 2008, it was located at Almácigo Bajo Ward in the municipality of Yauco (USFWS 2017, p. 9). The species is also now known to extend to the Municipality of Salinas, as evidenced by a specimen collected within the boundaries of the Puerto Rico National Guard's Camp Santiago (Acevedo-Rodríguez 2014, p. 15; see table below). This locality is at least 18.6 miles (30 kilometers (km)) east of the previously nearest known site at Punta Cucharas in the municipality of Ponce. Below, we discuss each of these areas in more detail.

TABLE OF CURRENTLY KNOWN NATURAL POPULATIONS AND NUMBER OF INDIVIDUALS (ADULTS AND SAPLINGS) OF EUGENIA WOODBURYANA IN PUERTO RICO

Population name based on geographical range	Subpopulation (locality) name	Number of known adults/saplings per subpopulation [1] and percent of the total known population [2]	Land conservation status	Ownership
Sierra Bermeja	La Tinaja Tract (within LCNWR).	808/271 (39.2%)	Protected	U.S. Fish and Wildlife Service.
Sierra Bermeja	Finca María Luisa (also known as Finca Escabi).	692/90 (28.4%)	Not protected	Private land under conservation easement with Para La Naturaleza. Threats not managed.
Sierra Bermeja	El Conuco (also known as Finca Sollins).	88/8 (3.5%)	Protected	Puerto Rico Conservation Trust (Para La Naturaleza).
Sierra Bermeja	Finca Lozada	300 estimated adults (10.9%)	Not protected	Private.
Almácigo Bajo, Yauco	Almácigo Bajo (Río Loco)	120/226 (12.6%)	Not protected	Private.
Guánica Commonwealth Forest.	Cañon Hoya Honda	10 estimated adults (0.36%)	Protected	PRDNER.
Guánica Commonwealth Forest.	Cañon Las Eugenias	31/8 (1.4%)	Protected	PRDNER.
Guánica Commonwealth Forest.	Cañon Murciélagos	27/39 (2.4%)	Protected	PRDNER.
Guánica Commonwealth Forest.	Cañon Las Trichilias	1 adult (0.04%)	Protected	PRDNER.
Montes de Barinas	Finca Catalá	1 adult (0.04%)	Not protected	Private.
Punta Cucharas (Ponce-Peñuelas).	Peñon de Ponce	20 adults (0.7%)	Not protected	Private.
Punta Cucharas (Ponce-Peñuelas).	Puerto Galexda	9 adults (0.3%)	Not protected	Private.
Punta Cucharas (Ponce-Peñuelas).	Gasoducto Sur right-of-way.	1 adult (0.04%)	Not protected	Private.
Salinas	Camp Santiago	1 adult (0.04%)	Not protected	Puerto Rico National Guard. Threats not managed.

[1] Seedlings not included as part of the population numbers because available data do not allow us to determine the percentage of seedlings that is recruited into the population. Existing data are sporadic, and the long-term survival of seedlings is uncertain due to natural thinning and environmental variables (*e.g.,* drought stress).

[2] The total known population is approximately 2,751 individuals, not including seedlings.

As shown in the table above, the largest population and suitable habitat of *E. woodburyana* is found in Sierra Bermeja, southwest Puerto Rico, a mountain range that covers approximately 3,706 acres (ac) (1,500 hectares (ha)) (USFWS 2011a, p. 17). *E. woodburyana* is known from at least four locations (subpopulations) within this area: La Tinaja Tract, Finca María Luisa (also known as Finca Escabi), Finca Lozada, and El Conuco (also known as Finca Sollins) (Envirosurvey 2020, p. 44). La Tinaja Tract is part of the LCNWR and occupies 263 ac (106.4 ha) in the foothills of Sierra Bermeja (USFWS 2011a, pp. 23, 26), and lies within the subtropical dry Forest life zone (Ewel and Whitmore 1973, p. 10; Weaver and Chinea 2003, p. 273). Although the species is not specific to this type of habitat, drainages provide moist conditions (mesic) favorable for its establishment, which may explain the higher abundance of the species at these sites. In fact, an inventory of listed plant species at La Tinaja Tract accounted for 808 adults and 271 saplings of *E. woodburyana* associated with those mesic habitats that favor germination and recruitment (Morales-Pérez 2013, p. 4; Monsegur-Rivera 2009–2018, pers. obs.; see table above). In addition, 141 seedlings were found in La Tinaja Tract, indicating evidence of recruitment (Morales- Pérez 2013, p. 7). The occurrence in Sierra Bermeja of multiple listed plants and rare endemics is the result of the little agricultural value of the steep slopes, hence little deforestation, which resulted in a refugia for those species, including *E. woodburyana.* Nonetheless, the lower slopes of Sierra Bermeja and surrounding valleys are subject to different land use practices that hinder the expansion of the species and associated native vegetation due to threats such as fires, invasive grasses, and grazing, along with dry climate conditions (Weaver and Chinea 2003, pp. 281–282).

Finca María Luisa is private land that ranges from the upper slopes of Sierra Bermeja south to the coast near La Pitahaya in the Boquerón Commonwealth Forest. This property is composed of a mosaic of habitats with different land uses that include ranching, hay production, and remnants of forested habitats. The forested habitat is adjacent to the boundaries of the LCNWR (La Tinaja Tract) and provides connectivity to the *E. woodburyana* subpopulations, particularly on La Tinaja Tract. An assessment of Finca María Luisa identified 629 adults and 90 saplings of *E. woodburyana* (Envirosurvey 2020, p. 59, 62; see table above), as well as 105 seedlings. However, there is no information on the survival of those seedlings. This property is currently under a conservation easement managed by the nongovernmental organization Para La Naturaleza, Inc. (PLN), the operational unit of The Conservation Trust of Puerto Rico (PLN 2013). This easement provides for the conservation of the natural resources of the property, including *E. woodburyana.* However, there are some agricultural practices (*e.g.,* grazing, forest conversion into grassland) that still threaten the species (PLN 2013, p. 56; USFWS 2017, p. 18; Envirosurvey 2020, p. 49). El Conuco is another property owned and managed for conservation by PLN in Sierra Bermeja where *E. woodburyana* is found (PLN 2014). This property is located on the west side of the mountain range, and in 2014, a subpopulation of *E. woodburyana* was reported with at least 41 individuals (USFWS 2014, p. 2). The latest survey indicates that there are at least 88 adults and 8 saplings of *E. woodburyana* on this property (Envirosurvey 2020, p. 62, 63; see table above). A total of 20 seedlings also were documented during this assessment, but there is no information on their long-term survival.

Finca Lozada is a private property located west of La Tinaja Tract, and with similar habitat to La Tinaja. In 2007, a rapid assessment of *E. woodburyana* was conducted on this property and estimated the subpopulation at around 300 individuals (USFWS 2017, p. 9).

E. woodburyana also was known from the area of Peñones de Melones in the Boquerón Ward of Cabo Rojo. This site is a western extension of the Sierra Bermeja habitat, but at lower elevations, and it has been subject to deforestation mainly for agriculture and urban development (USFWS 2017, p. 14). However, there are no current data on the status of this population, and *E. woodburyana* is presumed extirpated from this area due to the extensive deforestation and development that occurred during the early 2000s. In addition, there is a single record of the species from the CRNWR, but this locality has not been surveyed recently due to lack of information on the specific location of the individual. However, the CRNWR is currently a reintroduction site for *E. woodburyana.*

As previously stated, the known range of *E. woodburyana* increased when the species was located on private land (Río Loco population) at the Almácigo Bajo Ward near the southeast boundary of the Susúa Commonwealth Forest (SCF). This is the only population that occurs in the boundaries of the subtropical dry and moist forests life zones (Ewel and Whitmore 1973, pp. 25, 72). The latest information from this site indicates the *E. woodburyana* population is composed of at least 120 adults and 226 saplings (USFWS 2017, p. 9; see table above). Despite the relatively disturbed nature of this area, a total of 211 seedlings also were documented during the assessment, but their current survival is unknown (USFWS 2017, p. 9). In fact, due to the proximity of this population to the SCF, and the availability and continuity of suitable habitat, we would expect to find additional *E. woodburyana* individuals along the southeastern portion of the SCF.

The GCF is a natural area comprising one of the best remnants of subtropical dry forest vegetation in Puerto Rico (Monsegur-Rivera 2009, p. 3). Elevation ranges from 0 to 228 m (0 to 748 ft) above sea level (Murphy et al. 1995, p. 179), and the landscape includes a variable topography with a mixture of hills and deep canyons or ravines that provides adequate conditions for the occurrence of *E. woodburyana.* There are four localities within the GCF where subpopulations of this species have been documented: Cañón Hoya Honda, Cañón Murciélagos, Cañón Las Eugenias, and Cañón Las Trichilias (Monsegur-Rivera 2009–2018, pers. obs.; see table above). The currently known number of *E. woodburyana* individuals at the GCF is approximately 69 adults and 47 saplings (USFWS 2017, p. 8). Also, 31 seedlings were found in the GCF, but no information is available regarding their survival (USFWS 2017, p. 8).

The known range of *E. woodburyana* extends north to the hills along Montes de Barinas in a habitat similar to the GCF (Monsegur-Rivera 2009–2018, pers. obs.). This tract of privately owned lands is located primarily along Indios Ward in the municipality of Guayanilla, and Cambalache Ward in the municipality of Yauco. Due to the marginal agricultural value of these areas, the forest was partially logged for charcoal production and ranching; fortunately, the prime habitat for native and endemic plant species remained undisturbed (see *Unit 3* description in 79 FR 53315, September 9, 2014, on p. 53326). The forested habitats at Montes de Barinas and the GCF are separated by an agricultural valley along the Yauco River. In fact, this geographical range overlaps with the designated critical habitat of *Varronia rupicola* (see *Unit 3* descriptions in 79 FR 53315, September 9, 2014, on pp. 53326, 53339). The

number of individuals of *E. woodburyana* at this location is limited to one record (see table above). However, most of the habitat remains unexplored; thus, further surveys are necessary to determine the size of this population (Monsegur-Rivera 2009–2018, pers. obs.).

Similar habitat extends east to private lands in the area of Punta Cucharas, along Encarnación and Canas Wards between the municipalities of Peñuelas and Ponce in southern Puerto Rico. This area also lies within the designated critical habitat for *Varronia rupicola* (see *Unit 4* descriptions in 79 FR 53315, September 9, 2014, on pp. 53326, 53339). Here, *E. woodburyana* is known from at least three subpopulations: Peñon de Ponce, Puerto Galexda, and the former right-of-way of the proposed gas pipeline Gasoducto Sur, with an estimated minimum number of 30 individuals growing mainly along drainages on the northwest-facing slopes with greater moisture retention (Monsegur-Rivera 2009–2018, pers. obs.; USFWS 2017, p. 10; see table above). The current forest structure and absence of exotic plant species suggest this habitat has remained mainly undisturbed, explaining the presence of rare species like *Buxus vahlii* (Vahl's boxwood, an endemic species with limited seed dispersal mechanism) in the area. Thus, the presence of additional subpopulations of *E. woodburyana* in this area is very likely.

The newest record indicating the expansion of the species' known range is from a specimen collected at the Puerto Rico National Guard's Camp Santiago in the municipality of Salinas. This site is about 18.6 miles (30 km) east from the nearest known locality in Punta Cucharas in a habitat composed of remnants of native dry forest. Camp Santiago covers an area of 12,787.6 ac (5,175 ha) and is located south of the central mountain range of Puerto Rico (Acevedo-Rodríguez 2014, p. 15).

Population Summary

As summarized in the table above, the known populations of *E. woodburyana* (Sierra Bermeja, Almácigo Bajo, Yauco, Guánica Commonwealth Forest, Montes de Barinas, Punta Cucharas (Ponce-Peñuelas) and Salinas) comprise approximately 2751 adult and juvenile individuals. Based on the available information indicates at least 808 adults and 271 saplings of *E. woodburyana* occur within the boundaries of La Tinaja Tract within the LCNWR (Sierra Bermeja population) (Morales-Pérez 2013, p. 4; see table above). In addition, the subpopulation of Finca María Luisa is composed of at least 692 adults and 90 saplings (Envirosurvey 2020, p. 47; see table above). In the case of El Conuco, the subpopulation is 88 adults and 8 saplings (Envirosurvey 2020, p. 51; see table above). When evaluating the combined data from La Tinaja Tract, Finca María Luisa, El Conuco, and Finca Lozada as the whole Sierra Bermeja population, the total number of adults (1,888) and saplings (369) consists of 2,257 individuals within this population. In addition, at least 269 seedlings (144 in La Tinaja Tract, 105 in Finca Maria Lucia, and 20 in El Conuco) have been recorded in this population (Morales-Pérez 2013, p. 7; Envirosurvey 2020, pp. 47, 51). Although we recognize the occurrence of seedlings, we did not include them in the total number of *E. woodburyana* in this population because their fate is unknown due to the lack of long-term monitoring. For example, seedling survival can be compromised by environmental variables like droughts, particularly in the dry forest habitat where the species occurs. Still, 1,888 adult plants represents a demonstrable increase compared to the number known at the time when the species was listed (45 individuals) or even at the time the recovery plan was published (150 individuals in 1998). The presence of different size classes shows that the *E. woodburyana* population in Sierra Bermeja has been resilient to past and current threats (*e.g.,* unsustainable agricultural practices, grazing, fires, invasive plant species) as suggested by its natural recruitment, reflected in the actual number of adults and saplings. Based on aerial images, and because the vegetation structure in neighboring lands is similar to areas with documented presence of *E. woodburyana,* we anticipate the species extends beyond our surveyed area in Sierra Bermeja. Nonetheless, *E. woodburyana* appears to be absent from areas previously deforested and degraded to grasslands dominated by exotics (*e.g., Megathyrsus maximus* (guinea grass)), and it is mainly restricted to those areas that provide favorable conditions for its establishment (*e.g.,* drainages) (Weaver and Chinea 2003, entire; Morales-Pérez 2013, p. 4; Monsegur-Rivera 2009–2018, pers. obs.; Envirosurvey 2020, pp. 46, 51). Similar to Sierra Bermeja, the Almácigo Bajo (also known as Río Loco) population also shows evidence of natural recruitment and resiliency to previous habitat disturbance. The latest comprehensive survey of this population resulted in 346 individuals, corresponding to 120 adults and 226 saplings (USFWS 2017, p. 11; see table above). Despite the relatively disturbed nature of this area, it harbors a higher proportion of seedlings (38 percent) than that of Sierra Bermeja (10.5 percent) (USFWS 2016, p. 5; USFWS 2017, pp. 9, 10), which most likely is the result of the moist understory conditions in the drainages where the species is found that provide for better seed germination and seedling establishment. Nonetheless, even though this population is the more structurally proportionate, the recruitment of those seedlings into the population is uncertain.

At the GCF, the subpopulation at Cañón Murciélagos (also known as Dinamita Trail) is relatively small (*i.e.,* 27 adults and 39 saplings (USFWS 2016, p. 8). Further assessment of the subpopulation at Cañón Las Eugenias (also known as Cueva Trail) in the GCF found 31 adults and 8 saplings (USFWS 2016, p. 8). A third subpopulation at Cañón Hoya Honda is composed of about 10 adult individuals (Monsegur-Rivera 2009–2018, pers. obs.). A total of 31 seedlings were found at Cañón Murciélagos (29) and Cañón Las Eugenias (2) (USFWS 2019, p. 8), but their current survival is unknown. The populations of Montes de Barinas, Punta Cucharas, and Camp Santiago are recent additions to the species' known range, and further systematic inventories are needed in order to determine the extent and trends of these populations. Nonetheless, these very small populations are characterized by little or no recruitment (*e.g.,* Acevedo-Rodríguez 2014, p. 15).

Recovery

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be removed from the List of Endangered and Threatened Wildlife or the List of Endangered and Threatened Plants.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not regulatory documents and do not substitute for the determinations and

promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species, or to delist a species, is ultimately based on an analysis of the best scientific and commercial data available to determine whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, information on the species that was not known at the time the recovery plan was finalized may become available later. The new information may change the extent that criteria need to be met for recognizing recovery of the species. The recovery of species is a dynamic process requiring adaptive management that may, or may not, fully follow the guidance provided in a recovery plan.

The following discussion provides an analysis of the recovery criteria and goals as they relate to evaluating the status of the taxon.

Recovery Criteria

The recovery plan for this species did not provide downlisting criteria (USFWS 1998, entire). In 2019, the Service published an amendment to the original recovery plan, which amended the recovery criteria of this species by establishing that *E. woodburyana* will be considered for delisting when the following criteria are met (USFWS 2019, p. 4): (1) Threat reduction and management activities are implemented to a degree that the species will remain viable into the foreseeable future; (2) existing natural populations of *E. woodburyana* (6 populations) show a stable or increasing trend, as evidenced by natural recruitment and multiple age classes; and (3) within the historical range, at least three new populations of *E. woodburyana* are established on lands protected by a conservation mechanism that show a stable or increasing trend, evidenced by natural recruitment and multiple age classes. We apply our current understanding of the species' range, biology, and threats to these delisting criteria to support our rationale for why downlisting *E. woodburyana* is appropriate.

Recovery Criteria 1: Threat reduction and management activities are implemented to a degree that the species will remain viable into the foreseeable future.

Throughout the known range, the species still faces a wide variety of threats; however, some locations show improvement in management and protection activities are ongoing by a variety of partners. Overall, about 47 percent of the currently known *E. woodburyana* individuals occur within lands managed for conservation. As previously stated, the GCF is managed for conservation by PRDNER as recommended by the Master Plan for the Commonwealth Forests of Puerto Rico (DRN 1976, p. 56). In addition, *E. woodburyana* is currently listed as critically endangered under PRDNER regulations and was most recently evaluated in 2004 (PRDNER 2005, p. 52). Consequently, that agency reviews all proposed actions for the GCF that may adversely affect *E. woodburyana* and other listed species and their habitats within the GCF. There is evidence of impacts on seedlings (*e.g.,* uprooting, covered by sediment) of other species that share habitat with *E. woodburyana* at the GCF due to runoff and sediments resulting from hurricane María in September 2017 (Monsegur-Rivera 2018, pers. obs.). Hence, seedlings of *E. woodburyana* can also suffer these same impacts. Moreover, although this population may not face the same threats as in Sierra Bermeja because the habitat is protected, its expansion outside drainages may be limited by the dry climate of the forest characteristic of dry forests with recurrent disturbance (*e.g.,* Weaver and Chinea 2003, p. 281). However, during a rapid assessment of *E. woodburyana* conducted at the GCF, no changes in habitat or evidence of activities affecting this species were observed (USFWS 2017, p. 8).

As for LCNWR, in 1996, the Service acquired La Tinaja Tract, a 263-ac (106.4-ha) tract in the foothills of Sierra Bermeja (USFWS 2011a, pp. 23, 26). This land is now protected and managed for the conservation of natural resources, with a comprehensive conservation plan that includes measures for the protection and recovery of endangered and threatened species, including *E. woodburyana* (USFWS 2011a, p. 35; Service 2011b, p. 47). As part of an existing Service cooperative recovery initiative project, a new fence was built along the upper southeast and southwest boundaries of La Tinaja Tract to reduce habitat modification from cattle grazing (mostly trampling, which damages the species, erodes soil, and opens up space to invasive plant species), and to allow the recovery of native vegetation.

Recovery actions like land acquisition and the establishment of conservation easements also have been undertaken to prevent habitat loss and degradation, and potential population decline. For example, PLN has two natural protected areas in Sierra Bermeja: the conservation easement Finca María Luisa (755.6 ac (305.8 ha)), and the Natural Protected Area El Conuco (37.4 ac (15.1 ha)) (PLN 2013, 85 pp.; PLN 2014, 58 pp.). As discussed above, both properties harbor subpopulations of *E. woodburyana* (PLN 2014, p. 13; Envirosurvey 2020, p. 44). Habitat management practices implemented at El Conuco include cattle exclusion, firebreaks, and a reforestation plan, providing suitable conditions for natural recruitment and the expansion of the *E. woodburyana* population (PLN 2013, 85 pp.). However, in the case of the Finca María Luisa easement, the conservation practices included in the management plan developed by PLN for this property have not yet been implemented.

Information gathered post-listing indicated that the known range of *E. woodburyana* has expanded to new localities: Montes de Barinas, Almácigo Bajo, Punta Cucharas, and the Puerto Rico National Guard's Camp Santiago in the municipality of Salinas. These areas collectively comprise approximately 14 percent of the currently known number of adults and saplings of *E. woodburyana*. However, all these locations are subject to habitat destruction or modification as described below under Summary of Biological Status and Threats, making the species in these areas vulnerable to habitat encroachment or even extirpation. For instance, Almácigo Bajo is relatively disturbed by cattle grazing and fence post harvesting.

Therefore, threat reduction and management activities at Finca María Luisa or Finca Lozada, Montes de Barinas, Almácigo Bajo, Punta Cucharas, and the Puerto Rico National Guard's Camp Santiago have not been implemented to a degree that these *E. woodburyana* subpopulations are secure in the long term. We continue to work with partners to provide beneficial management practices (*e.g.,* firebreaks, fencing, reforestation) throughout the species' range, as well as to monitor *E.*

woodburyana and survey suitable habitat for new occurrences of this species. Further, we are also looking for opportunities to implement best management practices with private landowners to enhance habitat to establish additional *E. woodburyana* subpopulations. We consider recovery criterion 1 to have been partially met. Recovery criterion 2: existing natural populations of *E. woodburyana* show a stable or increasing trend.

We are seeing significant progress in achieving this criterion, but it has not yet been fully met. The presence of different size classes in three (*i.e.,* Sierra Bermeja, Almácigo Bajo, and GCF) out of the six existing *E. woodburyana* populations suggests a certain degree of stability, and that the species has been resilient to past and current threats at these sites. However, additional indicators related to population structure are still needed to indicate long-term stability.

For example, Sierra Bermeja is the largest known population, with 2,526 individuals, including seedlings, but the proportion of adults, saplings, and seedlings is 75, 14.5, and 10.5 percent, respectively. Despite being the largest population, its structure is skewed towards adult individuals, with low frequency of saplings and seedlings (Envirosurvey 2020, pp. 51–52). This leads us to expect reduced recruitment, which can have negative implications for the long-term viability of the population and the species. Additionally, microhabitat conditions make it unlikely the population can expand to adjacent native forest. In fact, recruitment is limited to the close proximity of parental trees, which is apparently driven by gravity in the drainages where the species is present (Morales-Pérez, 2013, p. 4). In an effort to improve the conditions of existing populations of *E. woodburyana,* the Service, PRDNER, and PLN have joint efforts to enhance or augment the natural population within Sierra Bermeja (*i.e.,* La Tinaja Tract and neighboring private lands). While we estimate that a timeframe of 10 to 15 years is needed for the planted individuals to reach reproductive size, this should increase the self-sustainability of the species and will help it withstand stochastic events (*e.g.,* severe droughts). Similar efforts are needed in other areas (*e.g.,* GCF, Montes de Barinas, Punta Cucharas, and Almácigo Bajo) to further improve the species' status and secure its representation rangewide. At present, however, the GCF *E. woodburyana* population appears stable (USFWS 2017, p. 8).

Similar to Sierra Bermeja, the *E. woodburyana* population in the GCF is mostly found in drainages dominated by native forest vegetation, which provides adequate habitat conditions (*i.e.,* humidity) for the establishment of seedlings and saplings. However, there is little information about the ability of *E. woodburyana* to survive stochastic events such as landslides and heavy sediment runoff, particularly in these drainages.

The population at Almácigo Bajo appears to be relatively large and stable, despite cattle grazing and fence post harvesting, with multiple age classes resulting from natural recruitment. This may be the result of the mesic understory conditions due to its geographical location in the transition between the subtropical dry and moist forest life zones (Ewel and Whitmore 1973, pp. 25, 72). The proportion of seedlings to adults observed in Almácigo Bajo (38 percent) is higher when compared to the Sierra Bermeja (10.5 percent) and GCF (21 percent) populations. In addition, the proximity of this population to suitable and protected habitat in the SCF provides favorable conditions for its natural expansion or for planting additional individuals (population enhancement) to assist its expansion. As mentioned previously, we are seeing significant progress in achieving this criterion, but it has not yet been fully met.

Recovery criterion 3: at least three new populations of *E. woodburyana* are established on lands protected by a conservation mechanism that show a stable or increasing trend

Efforts for this criterion are ongoing. Currently, the Service and other partners have initiated the establishment of a new *E. woodburyana* population at the CRNWR, where 191 *E. woodburyana* individuals had been planted by 2019 (Envirosurvey 2020, p. 17). This habitat is forested with native vegetation, has low intrusion of exotic grasses (*e.g., Megathyrsus maximus*), and provides moisture that would facilitate the establishment of seedlings. Also, the CRNWR maintains firebreaks along the boundaries of the refuge, which help protect this site from human-induced fires. Two years of monitoring after planting have shown a survival rate greater than 96 percent (Envirosurvey 2020, p. 17), demonstrating that the proper selection of reintroduction sites is critical to maximize the survival of planted material. Further efforts are needed to establish two new self-sustainable populations within the species' range. Therefore, we have not met this recovery criterion.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. In 2019, jointly with the National Marine Fisheries Service, the Service issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and the criteria for designating listed species' critical habitat (84 FR 45020; August 27, 2019). On the same day, the Service also issued final regulations that, for species listed as threatened species after September 26, 2019, eliminated the Service's general protective regulations automatically applying to threatened species the prohibitions that section 9 of the Act applies to endangered species (84 FR 44753; August 27, 2019). We collectively refer to these as the 2019 regulations.

However, on July 5, 2022, the U.S. District Court for the Northern District of California vacated the 2019 regulations (*Center for Biological Diversity* v. *Haaland,* No. 4:19–cv–05206–JST, Doc. 168 (N.D. Cal. July 5, 2022) (*CBD* v. *Haaland*)), reinstating the regulations that were in effect before the effective date of the 2019 regulations as the law governing species classification and critical habitat decisions. Subsequently, on September 21, 2022, the U.S. Circuit Court of Appeals for the Ninth Circuit stayed the district court's July 5, 2022, order vacating the 2019 regulations until a pending motion for reconsideration before the district court is resolved (*In re: Cattlemen's Ass'n,* No. 22–70194). The effect of the stay is that the 2019 regulations are the governing law as of September 21, 2022.

Due to the continued uncertainty resulting from the ongoing litigation, we also undertook an analysis of whether the proposal would be different if we were to apply the pre-2019 regulations. That analysis, which we describe in a separate memo in the decisional file and have posted on *https://www.regulations.gov,* concludes that we would have reached the same proposal if we had applied the pre-2019 regulations.

The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a

''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects. We consider these same five factors in downlisting a species from endangered to threatened (50 CFR 424.11(c)).

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species—such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions. It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The 5-year review (USFWS 2017) documents the results of our comprehensive biological status review for the species, including an assessment of the potential threats to the species. The following is a summary of the key results and conclusions from the 5-year review and information gathered since that time, including information provided in the proposed rule published on October 21, 2020 (85 FR 66906). The 5-year review can be found at Docket No. FWS–R4–ES–2019–0070 on *https://www.regulations.gov.*

Summary of Biological Status and Threats

Habitat Loss

Habitat destruction and modification were identified as factors affecting the continued existence of *E. woodburyana* when it was listed in 1994 (59 FR 46715; September 9, 1994). The area of Peñones de Melones in Cabo Rojo is the only historical site for which the Service has strong evidence that *E. woodburyana* was extirpated. This site was estimated to have 20 individuals (Breckon 1996, unpublished data) and was impacted by residential and tourist development, and by agricultural practices such as livestock grazing (USFWS 2017, p. 18). While the species now occupies significantly more area and localities than were known at the time of listing and 73 percent of these sites occur in protected areas, it still faces the threat of habitat destruction and modification in several populations as described below and in our October 21, 2020, proposed rule (85 FR 66906).

As previously discussed, the Sierra Bermeja range comprises the core known natural population of *E. woodburyana,* with about 82 percent of the currently known adults and saplings found in this area. Most of this mountain range was zoned by the Puerto Rico Planning Board as a District of Conservation of Resources and Rustic Soil Specially Protected, which has specific restrictions on development activities in order to protect the natural resources of the area (Junta de Planificación Puerto Rico (JPPR) 2009, pp. 151–153). This zoning designation allows agricultural activities and construction of residential development (JPPR 2009, p. 151; JPPR 2015, pp. 118–129). Therefore, landowners continue to affect the habitat through activities like cutting new access roads on their properties (Pacheco and Monsegur-Rivera 2017, pers. obs.).

In addition, deforestation for agricultural practices (*e.g.,* conversion of forested habitat to pasturelands) has led to invasion of exotic species like guinea grass (*Megathyrsus maximus*), thus promoting favorable conditions for wildfires that further adversely affect *E. woodburyana* habitat (Weaver and Chinea 2003, p. 281). Also, cattle, horses, and goats graze all over the Sierra Bermeja range, causing habitat modification by making trails while foraging on the slopes, which also increases erosion (Morales-Pérez 2013, p. 4; Envirosurvey 2016, p. 9; Lange and Possley 2017, p. 4; Envirosurvey 2020, p. 49). Cattle grazing has resulted in direct impacts to *E. woodburyana* due to predation and trampling of seedlings (Lange and Possley 2017, p. 4). In fact, cattle trails were observed through a patch of *E. woodburyana* at Finca María Luisa, and at La Tinaja Tract, horses trampled several planted individuals of the species (Morales-Pérez 2013, p. 7; Envirosurvey 2016, p. 8). Such impacts (*e.g.,* trampling and predation) from

livestock are likely one of the reasons for the low number of seedlings of *E. woodburyana* in Sierra Bermeja (Envirosurvey 2020, p. 49).

Currently, two of the four subpopulations in Sierra Bermeja are protected because they occur on lands managed for conservation (*i.e.,* La Tinaja Tract and El Conuco), representing approximately 43 percent of all known adults and saplings. The remaining two subpopulations (*i.e.,* Finca María Luisa and Finca Lozada) represent about 39 percent of all known adults and saplings, and are subject to habitat destruction and modification for agricultural practices, which most likely have eliminated some *E. woodburyana* individuals (USFWS 2017, p. 18). Based on a comparison of a recent aerial photograph (2019) of this area, habitat modification through bulldozing has occurred within the area identified for conservation in the conservation easement of Finca María Luisa (Monsegur-Rivera 2019, pers. obs.; PLN 2013, p. 56). In addition to direct impacts to the species, bulldozing results in habitat fragmentation and degradation that change the microhabitat conditions needed for the successful recruitment of *E. woodburyana.* It also facilitates the invasion of exotic plant species such as guinea grass (*Megathyrsus maximus*) that compete with *E. woodburyana* and promote favorable conditions for wildfires.

The *E. woodburyana* populations at Punta Cucharas, Montes de Barinas, and Almácigo Bajo occur in privately owned lands that are vulnerable to habitat modification. For example, the habitat in the municipalities of Peñuelas and Ponce, including the area of Punta Cucharas, has been fragmented by urban development (see 79 FR 53303, September 9, 2014). In this area, the species occurs in at least three forested drainages located just north and close to highway PR 2, or adjacent to the Puerto Rico Electric and Power Authority power line right-of-way. Urban development has expanded north of highway PR 2, modifying the suitable habitat for the species (USFWS 2017, p. 20). On October 4, 2011, areas with *E. woodburyana* individuals at Puerto Galexda (Ponce-Peñuelas) were bulldozed, and some individuals were removed (USFWS 2011c, entire; USFWS 2017, p. 20). The Service observed that sediment runoff from adjacent urban development was covering the bottom of the drainage and likely precluding the recruitment of *E. woodburyana* seedlings as the sediment buries the small plants and seeds (USFWS 2011c, p. 3).

In Montes de Barinas, *E. woodburyana* occurs on private properties subject to urban development, resulting in native dry forest encroachment, and thus isolation and possible extirpation of *E. woodburyana* individuals. These areas also are threatened by deforestation due to cattle grazing and the extraction of fence posts (Román-Guzmán 2006, pp. 1–2; Monsegur-Rivera 2005, pers. obs.; see 79 FR 53303, September 9, 2014).

The *E. woodburyana* population at Almácigo Bajo Ward in Yauco is located in a small forested drainage in a parcel of land used for cattle grazing, and adjacent to an abandoned quarry (USFWS 2017, p. 19), which could be reactivated. Approximately 80 percent of the property was cleared of vegetation, and its surroundings are under pressure by agricultural and urban development (USFWS 2017, p. 19). Habitat modification and adverse impacts to *E. woodburyana* individuals also have been documented as a result of fence post extraction from this site (Monsegur-Rivera 2011–2017, pers. obs.). In 2008, 72 seedlings and saplings of *E. woodburyana* were found in a human-made ditch located approximately 45 m (148 ft) downhill of the Almácigo Bajo population (USFWS 2017, p. 19). A total of 46 saplings from this area were transplanted into the SCF to avoid being impacted by a project of the Puerto Rico Aqueduct and Sewage Authority (USFWS 2017, p. 11). The latest account of the transplanting effort indicates that only 11 individuals survived, but they appear to be in good condition (USFWS 2017, p. 11).

Human-Induced Fires

Human-induced fires have been documented in *E. woodburyana* habitat, and were considered a threat to the species when listed (59 FR 46715, September 9, 1994; USFWS 2017, p. 23). Fires are not a natural event in the subtropical dry forests in Puerto Rico, and the native vegetation in the Caribbean is not adapted to this type of disturbance (Brandeis and Woodall 2008, p. 557; Santiago-García et al. 2008, p. 604). Human-induced fires could modify the landscape by promoting the establishment of exotic trees and grasses, and by diminishing the seed bank of native species (Brandeis and Woodall 2008, p. 557). For example, the exotic guinea grass is well-adapted to fires and typically colonizes areas previously covered by native vegetation before a fire event. Furthermore, the presence of guinea grass and other grass species increases the amount of fuel for, and hence the intensity of, the fires. Seedling mortality after fires is related to the differences in fuel loads and different fire intensities (Santiago-García et al. 2008, p. 607).

E. woodburyana populations occur on the driest region of Puerto Rico where fires are sometimes ignited accidentally or deliberately, particularly during the dry season. Human-induced fires are a current threat to this and other native vegetation in Sierra Bermeja, Almácigo Bajo, Punta Cucharas, and Camp Santiago in Salinas (Envirosurvey 2020, p. 52). In May 2019, a large wildfire extended from the southern lowlands of Sierra Bermeja to the upper forested hills into El Conuco, affecting an undetermined number of individuals of *E. woodburyana* and encroaching on suitable habitat for the species (Envirosurvey 2020, p. 52). In La Tinaja Tract, LCNWR staff maintains firebreaks on the lower slopes, reducing the chance of fires reaching the upper part of the tract.

The recently discovered site at Camp Santiago in Salinas is owned by the Puerto Rico National Guard (Acevedo-Rodríguez 2014, p. 15). The areas covered by vegetation at this camp are frequently impacted by human-induced fires, which may compromise the survival of *E. woodburyana* (Acevedo-Rodríguez 2014, p. 15). According to Acevedo-Rodríguez (2014, p. 2), the predominant vegetation type is grasslands dominated by guinea grass, which are maintained by human-induced fires and grazing animals.

Fires also have occurred in *E. woodburyana* habitat in Punta Cucharas, between the municipalities of Ponce and Peñuelas, where habitat disturbance due to urban development and the expansion of highway PR 2 has promoted the establishment of guinea grass (Monsegur-Rivera 2011 and 2013, pers. obs.). Camp Santiago is another area where fires, which occur near *E. woodburyana* on a yearly basis (Monsegur-Rivera 2009–2018, pers. obs.), have been identified as a threat to the species due to anthropogenic disturbance (Acevedo-Rodríguez 2014, p. 15). At the GCF, *E. woodburyana* seems to be protected from fires, as the species mostly occurs in mesic (humid) drainages dominated by native forested vegetation where the risk of fires is low (Monsegur-Rivera 2011, pers. obs.).

Competition From Nonnative Plant Species

Nonnative plant species are another threat to *E. woodburyana.* Some nonnative plants can be very aggressive and compete with native species for sunlight, nutrients, water, and ground cover (see 79 FR 53303, September 9, 2014, at pp. 53309–53310). Examples

include the exotic tree *Leucaena leucocephala,* which can remain as a dominant canopy species for at least 80 years (Wolfe 2009, p. 2), and guinea grass, which colonizes habitat and suppresses native vegetation (Rojas-Sandoval and Meléndez-Ackerman 2013, p. 489). Both *L. leucocephala* and guinea grass are fire-adapted species that have widely colonized *E. woodburyana* habitat and outcompete native vegetation (Monsegur-Rivera 2018, pers. obs.; Envirosurvey 2020, p. 46).

In addition, some exotic plants create favorable conditions for fires, as in Camp Santiago in Salinas, where degraded habitat is dominated by guinea grass, threatening *E. woodburyana* (Acevedo-Rodríguez 2014, p. 15). As demonstrated by the research conducted in the GCF, restoring degraded habitat to native vegetation may require decades, and, in some cases, such damage may be irreversible (Wolfe 2009, p. 2). Although the core *Eugenia woodburyana* individuals are found in protected areas dominated by native forest vegetation rather than invasive species, the threat of invasive or exotic plant species intruding into *E. woodburyana* habitat persists due to the vulnerability of the area to fires as explained above.

Based on the above information, we believe that human-induced fires and invasive plants are a threat to *E. woodburyana,* particularly to those populations extending into private lands where habitat modifications and human-induced fires commonly occur.

In summary, at present, the *E. woodburyana* population at the GCF occurs within an area managed for conservation, and thus it is not subject to habitat destruction and modification. The Sierra Bermeja population is the largest and is partially protected as some of the individuals occur either on Federal (*i.e.,* La Tinja Tract-LCNWR) or private lands managed for conservation (*i.e.,* El Conuco). The remaining four populations (*i.e.,* Almácigo Bajo, Montes de Barinas, Punta Cucharas, and Camp Santiago) occur on private and State lands currently threatened by habitat destruction and modification (*e.g.,* urban development; vegetation clearing; road construction; grazing and trampling by cattle, horses, and goats; and military maneuvers at Camp Santiago). Losing these populations would result in a reduction of the genetic representation and redundancy of the species.

In addition, human-induced fires and invasive species are considered as further stressors to the viability of *E. woodburyana.* Human-induced fires have been documented in *E. woodburyana* habitat, particularly on private lands where no fire management practices are implemented and have the potential to adversely affect the species. Invasive species can preclude the establishment of *E. woodburyana* as they are very successful competing for sunlight, nutrients, water, and ground cover. Establishment of invasive species is facilitated by disturbances caused by fires and habitat modification. Fortunately, there are *E. woodburyana* subpopulations in protected areas dominated by native forest vegetation that does not facilitate the invasion of exotic plant species. However, in lands where habitat modification activities do occur, invasive plant species colonize and make the habitat unsuitable for *E. woodburyana,* and also promote conditions for fires.

Existing Regulatory Mechanisms

In the final listing rule (59 FR 46715; September 9, 1994), we identified the inadequacy of existing regulatory mechanisms as one of the factors affecting the continued existence of *E. woodburyana.* At that time, the species had no legal protection because it had not been included in Puerto Rico's list of protected species. Once *E. woodburyana* was federally listed, it triggered the addition of the species as endangered to the Commonwealth's list of protected species (DRNA 2004, p. 52). Such Commonwealth regulations are expected to continue in place and protect the species despite its reclassification to threatened. If the territory would like to remove the species, it would need to go through a review process by the agency.

Presently, *E. woodburyana* is legally protected under Commonwealth's Law No. 241–1999 (see title 12 of the Laws of Puerto Rico at section 107 *et seq.* (12 L.P.R.A. sec. 107 *et seq.*)), known as *Nueva Ley de Vida Silvestre de Puerto Rico* (New Wildlife Law of Puerto Rico). The purpose of this law is to protect, conserve, and enhance both native and migratory wildlife species; declare property of Puerto Rico all wildlife species within its jurisdiction; and regulate permits, hunting activities, and exotic species, among other activities. This law also has provisions to protect habitat for all wildlife species, including plants. In 2004, the PRDNER approved Regulation 6766 or *Reglamento para Regir el Manejo de las Especies Vulnerables y en Peligro de Extinción en el Estado Libre Asociado de Puerto Rico* (Regulation 6766: To govern the management of threatened and endangered species in the Commonwealth of Puerto Rico). Article 2.06 of Regulation 6766 prohibits collecting, cutting, and removing, among other activities, listed plant individuals within the jurisdiction of Puerto Rico (DRNA 2004, p. 11). The provisions of Law No. 241–1999 and Regulation 6766 extend to private lands and will continue protecting *E. woodburyana* whether or not the species has protections under the Act.

As for the individuals found at the GCF, this area is protected under Law No. 133–1975 (12 L.P.R.A. sec. 191 *et seq.*), known as *Ley de Bosques de Puerto Rico* (Puerto Rico Forests' Law), as amended in 2000. Section 8(a) of this law prohibits cutting down, killing, bud pruning, uprooting, or otherwise injuring or deteriorating any tree, forest product, or vegetation within a Commonwealth Forest (12 L.P.R.A. sec. 198(a)) and thus reduces potential impacts to native vegetation including *Eugenia woodburyana.* The PRDNER also identified the GCF as a Critical Wildlife Area (CWA). The CWA designation constitutes a special recognition by the Commonwealth with the purpose of providing information to Commonwealth and Federal agencies about the conservation needs of these areas, and to assist permitting agencies in precluding adverse impacts as a result of a project's endorsements or permit approvals (PRDNER 2005, pp. 211–216).

The LCNWR and CRNWR are managed in accordance with the National Wildlife Refuge Improvement Act of 1997 (Pub. L. 105–57). The collection of plants on National Wildlife Refuges is prohibited under 50 CFR 27.51, and there are prohibitions concerning plants federally listed as endangered or threatened that occur on areas under Federal jurisdiction, as well as on other areas, in section 9 of the Act and implementing regulations. In addition, any habitat management or action (*e.g.,* research) within a National Wildlife Refuge requires a Special Use Permit in coordination with the Refuge manager, thus, reducing potential impacts to *E. woodburyana.* Additionally, the comprehensive conservation plans for LCNWR and CRNWR include measures for the protection and recovery of endangered and threatened species, including *E. woodburyana,* on these refuges (USFWS 2011a, p. 35; USFWS 2011b, p. 47).

Although there are legal mechanisms in place for the protection of *E. woodburyana* (*e.g.,* laws, regulations, zoning), sometimes the enforcement of such mechanisms on private lands is challenging (*e.g.,* USFWS 2019, pp. 29–31). For example, accidental damage (*e.g.,* by cutting, pruning, or mowing) or even extirpation of *E. woodburyana*

individuals may occur because private landowners may not be aware that it is a protected species (*e.g.,* fence posts harvesting in Almácigo Bajo (USFWS 2016, p. 8)). Another form of impact is from agriculture; for example, zoning may restrict subdivision of lots and dense urbanization in some areas where the species is present, but may allow agricultural practices that can result in habitat modification that can affect *E. woodburyana.* On the other hand, the known range of *E. woodburyana* has increased since the time of listing. The species has been recorded in new areas subject to agriculture and urban development (USFWS 2016, entire; USFWS 2017, pp. 18–21), and despite the existence of regulatory mechanisms, habitat modification has occurred in these newly documented areas (*e.g.,* Almacigo Bajo site; USFWS 2017, pp. 18–21).

Outside of the protections provided by the Act, as described above, the species is protected from collection and provided management considerations by the National Wildlife Refuge Improvement Act of 1997 on two refuges. In addition, the Commonwealth of Puerto Rico legally protects *E. woodburyana* as an endangered species, including protections to its habitat, through Commonwealth Law No. 241–1999 and Regulation 6766. When *E. woodburyana* is reclassified to threatened (see **DATES**, above), we do not expect it to be removed from legal protection by the Commonwealth. Although these protections extend to both public and private lands, protection of this species on private land is challenging. Habitat that occurs on private land is subject to pressures from grazing and development. Accidental damage or extirpation of individuals has occurred due to lack of awareness by private landowners or other parties on the property (Román-Guzmán 2006, pp. 25–33; USFWS 2016, entire). Habitat modifications continue to occur on private lands, which can increase the chances of sediment runoff and human-induced fires (and subsequent spread of nonnative vegetation). In short, this plant is now more abundant and widely distributed, and occurs largely on conservation land, so effects due to inadequacy of regulatory mechanisms have been reduced. However, the occurrences of this species on private land continue to need enforcement, attention, and increased outreach to explain the species' importance.

Small Population Size

At the time of listing (59 FR 46715; September 9, 1994), the Service considered small population size as a threat affecting the continued survival of *E. woodburyana* based on the species' limited distribution (*i.e.,* only three isolated populations known at that time) coupled with low number of individuals (*i.e.,* only 45 individuals throughout the species' range). Information about the distribution and abundance gathered since this species was listed shows that *E. woodburyana* is more abundant and widely distributed than previously thought (USFWS 2017, entire). Thus, we no longer consider limited distribution and low population numbers as threats to this species. Even though some of the known populations are small (*e.g.,* Montes de Barinas), there are other populations with large numbers of individuals (*e.g.,* Sierra Bermeja), and that show recruitment (*e.g.,* Almácigo Bajo), which with proper management will allow the species to persist into the future even if one of the very small populations is adversely affected.

Hurricanes and Other Weather Events

The islands of the Caribbean are frequently affected by hurricanes. Puerto Rico has been hit by four major hurricanes in recent years: Hugo (1989), Hortense (1996), Georges (1998), and María (2017). Successional responses to hurricanes can influence the structure and composition of plant communities in the Caribbean islands (Van Bloem et al. 2003, p. 137; Van Bloem et al. 2005, p. 572; Van Bloem et al. 2006, p. 517; Lugo 2000, p. 245). Examples of the visible effects of hurricanes on the ecosystem include massive defoliation, snapped and wind-thrown trees, large debris accumulations, landslides, debris flows, and altered stream channels (Lugo 2008, p. 368). Hurricanes can produce sudden and massive tree mortality, which varies among species, but average about 41.5 percent (Lugo 2000, p. 245). Hence, small populations of *E. woodburyana* may be severely impacted by hurricanes, sometimes resulting in extirpation of relic individuals. The recent hurricane María caused defoliation and uprooting of some *E. woodburyana* individuals planted at the CRNWR, and even though none have died, they are stressed due to the damage to the root system (Monsegur-Rivera, Service 2017, pers. obs.).

As an endemic to the Caribbean, *E. woodburyana* is adapted to tropical storms and the prevailing environmental conditions. However, the number of populations, and the small numbers of individuals in some populations (*e.g.,* Camp Santiago and Montes de Barinas), make some populations and thereby the species vulnerable to stochastic and catastrophic events such as hurricanes. Based on observations of the damage caused by hurricane María, small *E. woodburyana* populations, such as those of the GCF, Montes de Barinas, Punta Cucharas, and Camp Santiago, may be extirpated if any of those areas is directly impacted by a category 4 or 5 hurricane that will cause high levels of wind, knocking over trees or uprooting them leading to stress or possible death. Therefore, we believe hurricanes can be a threat to *E. woodburyana,* particularly to small populations dominated by adult reproductive individuals, because intensity and frequency of these natural disturbances is expected to increase due to climate change (see *Climate Change,* below).

Landslides and sediment runoff associated with atmospheric disturbances may also pose a threat to *E. woodburyana,* particularly in Sierra Bermeja, GCF, Punta Cucharas, and Almácigo Bajo (Morales-Pérez 2013, pp. 5, 12). At these locations, adult mature individuals, as well as seedlings and saplings, are mostly found on steeper slopes or along the bottom of deep natural drainages (USFWS 2016, p. 5). High rainfall associated with tropical storms and hurricanes may cause floods that, in combination with steep topography and highly erodible soils, may lead to mass wasting events (*e.g.,* land, mud, and debris slides; Lugo 2008, p. 368). In fact, in September 2009, three landslides resulting from heavy rains were recorded in Sierra Bermeja adjacent to the area where *E. woodburyana* occurs (USFWS 2010, p. 16). Moreover, surveyors observed that runoff and erosion exposed the roots of *E. woodburyana* in Sierra Bermeja (Envirosurvey 2020, p. 51). As mentioned above, the Service has evidence of impacts to seedling recruitment by sediment runoff from adjacent urban development in the area of Punta Cucharas in Ponce (USFWS 2011c, p. 2). Events like this may be exacerbated by severe rains associated with hurricanes or storms. Recent observations identified uprooted and buried seedlings of the endangered palo de rosa (*Ottoschulzia rhodoxylon*) and bariaco (*Trichilia triacantha*), which share habitat with *E. woodburyana* in the GCF, due to sediment runoff and flooding events associated with hurricane María on September 20, 2017 (Monsegur-Rivera 2018, pers. obs.). Similar observations have been recorded from the area of Punta Cucharas, where seedlings of bariaco were adversely affected by sediment runoff (USFWS

2011c, entire). There is little information about *E. woodburyana's* ability to survive stochastic events like landslides and heavy sediment runoff. However, the small size of some populations and the seedling establishment on moist drainages mean that events such as those mentioned may have adverse impacts on this species.

Climate Change

The Intergovernmental Panel on Climate Change (IPCC) concluded that evidence of warming of the climate system is unequivocal (IPCC 2014, p. 3). Observed effects associated with climate change include widespread changes in precipitation amounts and aspects of extreme weather including droughts, heavy precipitation, heat waves, and a higher intensity of tropical cyclones (IPCC 2014, p. 4). Rather than assessing climate change as a single threat in and of itself, we examined the potential consequences to the species' viability and its habitat that arise from changes in environmental conditions associated with various aspects of climate change. Based on what is known about the distribution of *E. woodburyana* and the habitat where it is more abundant (*i.e.,* steep slopes and bottom of deep natural drainages), we believe climate change can have adverse effects on this species, particularly in its natural recruitment, and hence the expansion of populations.

We examined a downscaled model for Puerto Rico based on three IPCC global emissions scenarios from the CMIP3 data set: mid-high (A2), mid-low (A1B), and low (B1) as the CMIP5 data set was not available for Puerto Rico at that time (Henareh Khalyani et al. 2016, pp. 267, 279–280). These scenarios are generally comparable and span the more recent representative concentration pathways (RCP) scenarios from RCP 4.5 (B1) to RCP 8.5 (A2) (IPCC 2014, p. 57). Under all these scenarios, emissions increase, precipitation declines, and temperature and total dry days increase, resulting in extreme drought conditions that would result in the conversion of sub-tropical dry forest into dry and very dry forest (Henareh Khalyani et al. 2016, p. 280).

There is high uncertainty in precipitation modeling for the region, as Caribbean rainfall is influenced by complexities in large-scale atmosphere and ocean dynamics (Henareh Khalyani et al. 2016, p. 275). Modeling shows dramatic changes to Puerto Rico through 2100; the divergence in these projections increases dramatically after mid-century, making projections beyond 20 to 30 years more uncertain (Henareh Khalyani et al. 2016, p. 275). By mid-21st century, Puerto Rico is predicted to be subjected to a decrease in rainfall, along with increase drought intensity (Henareh Khalyani et al. 2016, p. 265; U.S. Global Change Research Program (USGCRP) 2018, p. 20:820). As precipitation decreases influenced by warming, it will tend to accelerate the hydrological cycles, resulting in wet and dry extremes (Jennings et al. 2014, p. 4; Cashman et al. 2010, p. 1). There are indications that the western region of Puerto Rico, where *E. woodburyana* occurs, has experienced negative trends in annual rainfall (PRCCC 2013, p. 7).

Downscaled general circulation models (GCMs) developed by Henareh Khalyani et al. (2016, p. 275) predicted dramatic shifts in the life zones of Puerto Rico with potential loss of subtropical rain, moist, and wet forest, and the appearance of tropical dry and very dry forests are anticipated. This shift in life zones may result in potential species migration to higher elevations; however, the extent of the species' ability to redistribute will depend on dispersal capability and forest connectivity (Henareh Khalyani et al. 2019, p. 11). Subtropical dry forests are already subject to water deficit for 10 months of the year and are expected to become drier in the future; particularly in the Caribbean, where oceans have a largest influence on local precipitation, climate models consistently project significant drying by the middle of the century (Miller and Lugo 2009, p. 86; USGCRP 2018, p. 20:820). For example, droughts may compromise seedling recruitment by reducing seed viability and increasing seedling mortality. We have already seen a low proportion of *E. woodburyana* seedlings and saplings at lower elevations and outside drainages in areas like Sierra Bermeja and Punta Cucharas that are probably associated with anthropogenic impacts (*e.g.,* human-induced fires, habitat modification). The inability of *E. woodburyana* to migrate to wetter habitats due to low seed dispersal capability and the lack of forest connectivity would reduce its survival.

Prolonged droughts can exacerbate those anthropogenic impacts by changing the microclimate conditions (*i.e.,* temperature and soil moisture retention) favorable for the establishment of seedlings, thus reducing the recruitment of *E. woodburyana*. In Almácigo Bajo, where the Service has recorded a high proportion of seedlings and saplings compared to adults (Monsegur-Rivera 2009–2018, pers. obs.; see table above), mesic (humid) environmental conditions favor the natural recruitment of the species, contrasting with the low proportion of seedlings versus adult individuals of Sierra Bermeja (despite the partial protection of the habitat), where overall environmental conditions are drier. The lowlands and valleys surrounding Sierra Bermeja were covered by continuous forest, and these areas were deforested for agriculture, which changed the microhabitat conditions and the moisture retention of the habitat in which *E. woodburyana* evolved. For example, the populations of *E. woodburyana* at El Conuco that are located on south-facing slopes and more disturbed sites show basically no recruitment when compared to the individuals of the same populations located on the north-facing slopes, which are a dense forested habitat with moist conditions and less intrusion by exotic species.

Climate model simulations indicate an increase in global tropical cyclone intensity as well as an increase in the number of very intense tropical cyclones (USGCRP 2018, p. 2:8). Thus, it is expected that the Caribbean will experience an increase in the amount of precipitation and extreme winds produced during hurricane events (Herrera et al. 2018, p. 1). Hurricanes, followed by extended periods of drought caused by climate change, may result in changes to microclimate that could allow other highly adaptive invasive species to establish and become harmful to the system (Lugo 2000, p. 246; Hopkinson et al. 2008, p. 255; IPCC report 2018, p. 244). In fact, as stated above, species like the exotic guinea grass can colonize and spread into *E. woodburyana* habitat after a disturbance, increasing fire propensity and altering microclimate and nutrient cycling of the habitat on which *E. woodburyana* depends. Additionally, increased heavy precipitation can augment the probability of landslides and sediment runoff in those steep areas where *E. woodburyana* is abundant and severely affect the species (Morales-Pérez 2013, pp. 5, 12). In general, increasing hurricane intensity and frequency, along with *E. woodburyana's* small populations, a low number of individuals in most populations, the species' low recruitment rate, and habitat degradation and fragmentation, are likely to have adverse consequences for this species and its habitat.

As stated above, projected climate conditions will likely have direct or at least indirect adverse effects on *E. woodburyana* and its habitat. Some general patterns associated with forest ecosystems in Puerto Rico (PRCCC 2013, p. 14) that can affect *E. woodburyana,* are increased seasonality in precipitation and decreased soil moisture availability, which will alter

flowering and fruiting patterns; affect seedling germination and survival; and result in changes in forest species composition, structure, and ecological functions. Also, intense storms will increase disturbance, changing plant succession and biomass, leading to novel communities (likely dominated by exotic plant species). Despite the evidence that some terrestrial plant populations have the ability to adapt and respond to changing climatic conditions (Franks et al. 2013, entire), a long-term monitoring of known *E. woodburyana* populations is needed to determine whether this species will be resilient to, or be able to adapt to, these stressors.

In summary, the limited distribution and low number of individuals were considered a threat to *E. woodburyana* when listed. Recent information indicates the species is more abundant and widely distributed than previously thought. Currently, other natural and manmade factors, such as hurricanes and climate change are considered stressors to *E. woodburyana*.

Hurricanes can result in massive mortality of trees, and particularly can affect or even extirpate small populations of *E. woodburyana*. Hurricane María caused defoliation and uprooting of *E. woodburyana* planted individuals at the CRNWR (Monsegur-Rivera 2017, pers. obs.), however population-level effects were not verified. Stochastic events, such as landslides and heavy sediment runoff, particularly caused by hurricanes, also can threaten *E. woodburyana* because of the occurrence of core populations of this species in steep areas in Sierra Bermeja where landslides have been documented near them.

Also, it is expected that *E. woodburyana* will be affected by changes in climatic conditions. Effects associated with climate change include droughts, heavy precipitation, and intense tropical storms and hurricanes. For *E. woodburyana,* a reduction in precipitation in a subtropical dry forest where precipitation is already reduced, may compromise its phenology, seed viability, seedling recruitment, and seedling survival. Intense hurricanes, followed by extended periods of drought may result in changes in microclimate conditions that can favor the establishment invasive species that can compete with *E. woodburyana*. Additionally, increased heavy precipitation during hurricanes can produce landslides and sediment runoff in steep areas where *E. woodburyana* occurs, affecting its survival and recruitment (Morales-Pérez 2013, pp. 5, 12; Envirosurvey 2020, p. 51). Moreover, extreme wind events may result in the direct mortality of individuals and extirpation of small populations (*e.g.,* Montes de Barinas and Salinas). Overall, the effects of a changing climate on *E. woodburyana* can be exacerbated by its reduced number of populations, low number of individuals in most populations, and habitat degradation and fragmentation, which can affect the viability of the species into the future.

Summary of Threats

We have carefully assessed the best scientific and commercial information available regarding the threats faced by *E. woodburyana* in developing this rule. Based on the analysis above, even though we no longer consider limited distribution as a threat to this species, we believe that habitat destruction and modification (*e.g.,* forest conversion into pasturelands) on privately owned lands and other factors, such as human-induced fires, livestock, invasive plant species, hurricanes, and climate change (droughts), continue to threaten *E. woodburyana* populations despite these threats being reduced in some areas.

Species viability, or the species' ability to survive long term, is related to the species' ability to withstand catastrophic population and species-level events (redundancy), to adapt to changing environmental conditions (representation), and to withstand stochastic disturbances of varying magnitude and duration (resiliency). The viability of a species is also dependent on the likelihood of new stressors or continued threats now and in the future that act to reduce a species' redundancy, representation, and resiliency. Redundancy of populations is needed to provide a margin of safety for a species to withstand catastrophic events.

We further evaluated the biological status of this species both currently and into the future, considering the species' viability as characterized by its resiliency, redundancy, and representation. *E. woodburyana* has demonstrated resilience to both natural and anthropogenic disturbances. However, seedlings remain susceptible to the effects of droughts and habitat modification, which can affect the recruitment and long-term viability of *E. woodburyana*.

Currently, three (*i.e.,* Sierra Bermeja, GCF, and Almácigo Bajo) of the six known *E. woodburyana* populations show some degree of natural recruitment. The observed resiliency of the species may have occurred in part due to the availability of suitable habitat where some of the subpopulations are found, which allowed some recruitment. To further natural recruitment and provide even greater resiliency, more habitat protection and enhancement is needed. This would increase connectivity between subpopulations, maximizing the likelihood of crosspollination and gene flow, increasing fruit production and viable seeds. In addition, the remaining small and isolated populations (*i.e.,* Monte Barinas, Punta Cucharas, and Camp Santiago) need to be enhanced and protected.

We have no data on the genetic variability of *E. woodburyana* to inform representation. However, this species occurs in a wide range of habitats and environmental conditions, suggesting that the species was widely distributed in the past and it may have an ample genetic plasticity that would allow the species to adapt to different habitat and environmental changes. Although *E. woodburyana* is still thriving in these environments, its representation basically relies on the genetic contribution of only two populations, Sierra Bermeja and GCF, as these subpopulations are well connected. The remaining four populations are isolated, with only a very few individuals and lack of recruitment, except for the Almácigo Bajo population. This population occurs on a private land adjacent to a former quarry and where harvesting of *E. woodburyana* and other species for fence posts has been documented (USFWS 2017, p. 19). The loss or reduction of the Almácigo Bajo population would represent an important impact to the species' conservation due to its higher recruitment rate, and its presumed genetic uniqueness as it is the only one occurring within the subtropical moist forest life zone. Three of the known populations are small in numbers, isolated, and not effectively reproducing. Therefore, we believe the overall representation of *E. woodburyana* is low to moderate.

We consider that *E. woodburyana's* redundancy has increased since listing but remains low to moderate as it is only known from six populations throughout its geographical range. Moreover, three of these populations—Montes de Barinas (1 adult individual), Punta Cucharas (30 adult individuals), and Camp Santiago (1 adult individual)—are very small with no current evidence of natural recruitment, making them more vulnerable to catastrophic events such as human-induced fires, hurricanes, and droughts, which affect seedling establishment (Acevedo-Rodríguez 2014, p. 15). In fact, *E. woodburyana* has not been observed naturally expanding or

colonizing into degraded habitat outside the areas where it is known to occur, particularly where the largest populations are found (*i.e.,* Sierra Bermeja, GCF, and Almácigo Bajo). The populations on Montes de Barinas and Camp Santiago are the most vulnerable to extirpation if not managed and enhanced. The loss of the Montes de Barinas, Punta Cucharas, and Camp Santiago individuals (the easternmost populations) will reduce the redundancy of the species.

Although population numbers and abundance of *E. woodburyana* have increased, and some identified threats have decreased, our analysis indicates that, because of the remaining threats and stressors, the species remains likely to become in danger of extinction in the foreseeable future throughout all of its range. Based on biological factors and stressors to the species' viability, we consider 30 years to be the foreseeable future within which we have a reasonable degree of confidence in the predictions. The foreseeable future for the individual threats varies. Projections out to the year 2100 show increases in temperature and decreases in precipitation (Henareh Khalyani et al. 2016, pp. 274–275). However, divergence in temperature and precipitation projections increases dramatically after mid-century, depending on the scenario (Henareh Khalyani et al. 2016, p. 275), making projections beyond 20 to 30 years uncertain. Therefore, our ability to predict stressors associated with climate change is reduced beyond mid-century. Thus, using 30 years as the foreseeable future accounts for the effects of predicted changes in temperature, the shifting of life zones, and increasing droughts. Additionally, the species has been listed for more than 25 years, so we have a baseline to understand how populations have performed in that period.

This time period includes multiple generations of the species and allows adequate time for impacts from conservation efforts or changes in threats to be observed through population responses. For example, this timeframe accounts for the species' reproductive biology because it reflects the time required by an individual plant of *E. woodburyana* to reach a reproductive size and effectively contribute to the next generations. It accounts for reaching maturity, the probability of flowering, effective cross-pollination, setting viable fruits, seed germination, and seedling survival and establishment, considering environmental stochastic events such as drought. Furthermore, the established timeframe provides for the design and implementation of conservation strategies to protect and enhance currently known populations. It also accounts for continued collaboration with partners (*e.g.,* PRDNER and PLN) to implement effective propagation and reintroduction of *E. woodburyana,* and to implement best management practices to reduce impacts from agricultural practices that will reduce incidence of human-induced fires and promote habitat connectivity.

Determination of *Eugenia woodburyana*'s Status

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for determining whether a species meets the definition of ''endangered species'' or ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we carefully examined the best scientific and commercial information available regarding the past, present, and future threats faced by this plant. We reviewed the information available in our files and other available published and unpublished information, and we consulted with recognized experts and State/Territory agencies. In considering factors that might constitute threats to a species, we must look beyond the exposure of the species to a factor to evaluate whether it responds to the factor in a way that causes impacts to the species or is likely to cause impacts in the future. If a species responds negatively to such exposure, the factor may be a threat, and, during the status review, our aim is to determine whether impacts are or will be of an intensity or magnitude to place the species at risk. The factor is a threat if it drives, or contributes to, the risk of extinction of the species such that the species warrants listing as an endangered or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely affected could suffice. In sum, the mere identification of factors that could affect a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors act on the species to the point that the species meets the definition of an endangered or threatened species.

At the time of listing (59 FR 46715; September 9, 1994), the known range of *E. woodburyana* consisted of 45 individuals distributed among 3 localities in southwestern Puerto Rico. The most serious threats to such a small number of individuals were habitat destruction and modification, inadequacy of existing regulatory mechanisms, and limited distribution. Currently, *E. woodburyana* exists across a broader geographic range in six populations composed of several subpopulations. Increased survey efforts and implementation of recovery actions have resulted in more occupied habitat identified, leaving open the potential of finding even more *E. woodburyana* individuals. Protection under the Act, as well as Commonwealth laws and regulations, has reduced unauthorized take of the species, although accidental damage to the species has occurred due to lack of knowledge of the species by private landowners. Also, about 47 percent of the total known natural adults and saplings are found on Federal, Commonwealth, and private lands managed for conservation and where the species is protected.

Although now known to be more widespread and abundant than previously thought, the other 53 percent of known adult and saplings occur on lands where they are threatened by habitat destruction and modification (*e.g.,* conversion of forested habitat into pasturelands; grazing by cattle, horses, and goats; and urban development). In addition, recent information indicates that threats from invasive species, human-induced fires, droughts, hurricanes, landslides, and sediment runoff are currently acting upon *E. woodburyana*. Some of these threats could be more severe for the populations on lands where, for example, there are no fire management prevention practices implemented,

making the species more vulnerable to impacts.

We have determined that the previously recognized impacts to *E. woodburyana* from inadequate regulatory mechanisms that occurred prior to listing in 1994 by the Commonwealth of Puerto Rico have been reduced, and limited distribution is no longer impacting *E. woodburyana.* In summary, there continues to be concern about the present or threatened destruction, modification, or curtailment of *E. woodburyana'*s habitat or range (specifically, conversion of forested land into pasturelands; grazing by cattle, horses, and goats; and urban development) and other natural or manmade factors affecting *E. woodburyana'*s continued existence (specifically, invasive species, human-induced fires, droughts, hurricanes, landslides, and sediment runoff) throughout the species' known range, particularly for those populations on private lands. The existing regulatory mechanisms are not adequate to address these threats at this time. The species is not affected by stressors related to overcollection, disease, or predation. Still, none of the identified threats is an imminent threat or of a magnitude such that the taxon warrants endangered status across its range. Thus, after assessing the best available information, we conclude that *E. woodburyana* is not currently in danger of extinction throughout all of its range, but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 435 F. Supp. 3d 69 (D.D.C. 2020) (*Center for Biological Diversity*), vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for *E. woodburyana,* we address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

For *E. woodburyana,* we considered whether the threats are geographically concentrated in any portion of the species' range. We examined the following threats: Habitat destruction and modification (particularly by urban development and grazing by cattle, horses, and goats); human-induced fires; invasive species; hurricanes, landslides, and sediment runoff; and the effects of climate change (*e.g.,* prolonged droughts and expected shifts of life zones). As discussed above, these threats are acting upon the species across its range. We have identified that habitat modification is threatening four of the six *E. woodburyana* known populations. In addition, human-induced fires and invasive plant species are considered as further stressors to the viability of *E. woodburyana,* particularly on private lands throughout the known range of the species where no fire management practices are implemented. It is also expected that *E. woodburyana* will be affected by changes in climatic conditions, particularly by generalized changes in precipitation and drought conditions, and by the shifting of life zones, as suggested by downscaled models developed for Puerto Rico. In fact, climate change is expected to result in more intense hurricanes and extended periods of droughts, and effects to *E. woodburyana* from these will be exacerbated by a reduced number of the species' populations, the low number of individuals in most populations, and habitat degradation and fragmentation. Small populations are scattered throughout the range of the species and many are recently discovered. We have no evidence at present to say that these small populations are the result of a concentration of threats, instead, it appears it may simply represent increased survey effort in previously under-surveyed areas. The threats listed above either occur throughout the range or may affect populations in ways we cannot predict well, at present, therefore we have no evidence of a concentration of threats in any portion of the species range. Thus, there are no portions of the species' range where the species has a different status from its rangewide status. Therefore, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy, including the definition of ''significant'' that those court decisions held to be invalid.

Determination of Status

Our review of the best available scientific and commercial information indicates that *E. woodburyana* does not meet the definition of an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act, but this plant does meet the definition of a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act. Therefore, we are downlisting *E. woodburyana* from endangered to threatened on the List of Endangered and Threatened Plants.

Available Conservation Measures

Conservation measures provided for species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and

threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks.

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, Territory, and Tribal lands where appropriate. Funding for recovery actions could become available from a variety of sources, including Federal budgets, State programs, and cost share grants from non-Federal landowners, the academic community, and nongovernmental organizations. We invite you to submit any new information on this species whenever it becomes available (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species. If a Federal action may affect a listed species, the responsible Federal agency must enter into consultation with the Service.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy. The Act allows the Secretary to promulgate protective regulations for threatened species pursuant to section 4(d) of the Act. We are finalizing a set of regulations to provide for the conservation of the species in accordance with section 4(d). This rule, which includes a description of the kinds of activities that would or would not constitute a violation, complies with this policy.

II. Final Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (*see State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to [her] with regard to the permitted activities for those species. [She] may, for example, permit taking, but not importation of such species, or [she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising its authority under section 4(d) of the Act, the Service has developed a rule that is designed to address *E. woodburyana's* specific threats and conservation needs. Although the statute does not require the Service to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the *E. woodburyana.* As discussed above under Summary of Biological Status and Threats, the Service has concluded that *E. woodburyana* is at risk of extinction within the foreseeable future primarily due to habitat destruction and modification (urban development and grazing by cattle, horses, and goats); human-induced fires; and invasive species. Additionally, other natural or manmade factors like hurricanes, landslides, sediment runoff, and the effects of climate change cause the species to be in the risk of extinction within the foreseeable future. The provisions of this 4(d) rule promote the conservation of *E. woodburyana* by encouraging the conservation of the habitat considering land use and the

species' needs. The provisions of this rule are one of many tools that the Service will use to promote the conservation of *E. woodburyana*.

Provisions of the 4(d) Rule

This 4(d) rule will provide for the conservation of *E. woodburyana* by prohibiting the following activities, except as otherwise authorized or permitted: Import or export; removing and reducing to possession *E. woodburyana* from areas under Federal jurisdiction; maliciously damaging or destroying the species on any area under Federal jurisdiction; removing, cutting, digging up, or damaging or destroying the species on other area in knowing violation of any law or regulation of the Territory or in the course of any violation of a Territorial criminal trespass law; delivering, receiving, carrying, transporting, or shipping the species in interstate or foreign commerce in the course of a commercial activity; and selling or offering for sale the species in interstate or foreign commerce.

As discussed above under Summary of Biological Status and Threats, the present or threatened destruction, modification, or curtailment of its habitat or range (specifically, urban development; grazing by cattle, horses, and goats; human-induced fires; and invasive species), the inadequacy of existing regulatory mechanisms, and other natural or manmade factors affecting its continued existence (specifically, hurricanes, landslides, sediment runoff, and the effects of climate change) are affecting the status of *E. woodburyana*. A range of activities have the potential to impact *E. woodburyana,* including, but not limited to, habitat conversion from forested habitat to pasture for grazing, fence posts harvesting, and land clearing for development. Regulating these activities will help preserve the species' remaining populations, slow their rate of potential decline, and decrease synergistic, negative effects from other stressors.

Despite these prohibitions regarding threatened species, we may under certain circumstances issue permits to carry out one or more otherwise-prohibited activities, including those described above. The regulations that govern permits for threatened plants state that the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened species (50 CFR 17.72). Those regulations also state that the permit shall be governed by the provisions of § 17.72 unless a special rule applicable to the plant is provided in §§ 17.73 to 17.78. Therefore, permits for threatened species are governed by the provisions of § 17.72 unless a species-specific 4(d) rule provides otherwise. However, under our recent revisions to § 17.71, the prohibitions in § 17.71(a) will not apply to any plant listed as a threatened species after September 26, 2019. As a result, for threatened plant species listed after that date, any protections must be contained in a species-specific 4(d) rule. We did not intend for those revisions to limit or alter the applicability of the permitting provisions in § 17.72, or to require that every species-specific 4(d) rule spell out any permitting provisions that apply to that species and species-specific 4(d) rule. To the contrary, we anticipate that permitting provisions would generally be similar or identical for most species, so applying the provisions of § 17.72 unless a species-specific 4(d) rule provides otherwise would likely avoid substantial duplication. Under 50 CFR 17.72 with regard to threatened plants, a permit may be issued for the following purposes: for scientific purposes, to enhance propagation or survival, for economic hardship, for botanical or horticultural exhibition, for educational purposes, or for other purposes consistent with the purposes and policy of the Act. Additional statutory exemptions from the prohibitions are found in sections 9 and 10 of the Act.

The Service recognizes the special and unique relationship with our State and Territorial natural resource agency partners in contributing to conservation of listed species. State and Territorial agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State and Territorial agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Service in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Service shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State or Territorial conservation agency which is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, will be able to conduct activities designed to conserve *E. woodburyana* that may result in otherwise prohibited activities for plants without additional authorization.

The Service recognizes the beneficial and educational aspects of activities with seeds of cultivated plants, which generally enhance the propagation of the species, and therefore will satisfy permit requirements under the Act. The Service intends to monitor the interstate and foreign commerce and import and export of these specimens in a manner that will not inhibit such activities, providing the activities do not represent a threat to the survival of the species in the wild. In this regard, seeds of cultivated specimens will not be regulated provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container (*e.g.,* the seeds could be moved across State lines or between territories for purposes of seed banking or use for outplanting without additional regulations).

Nothing in this 4(d) rule will change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of *E. woodburyana*. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service.

Effects of This Rule

This rule revises 50 CFR 17.12(h) to reclassify *E. woodburyana* from endangered to threatened on the Federal List of Endangered and Threatened Plants. It also recognizes that this plant is no longer in danger of extinction throughout all or a significant portion of its range. This reclassification does not significantly change the protections afforded to this species under the Act. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, continue to apply to *E. woodburyana*. Federal agencies are required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect *E. woodburyana*.

As applicable, recovery actions directed at *E. woodburyana* will continue to be implemented as outlined in the recovery plan for this plant (USFWS 1998, entire). Highest priority actions (also recommended as future actions in our 5-year review (USFWS 2017)) include:

(1) Develop more measurable and objective criteria to delist this species based on best available information;

(2) Continue conducting comprehensive surveys for this species within traditional and non-traditional sites to determine more details on

abundance and distribution of the species;

(3) Promote conservation agreements with private landowners to protect and enhance existing populations;

(4) Work closely with the PRDNER and landowners to ensure the protection of the species and its habitat on private lands; and

(5) Continue implementing fire prevention practices in Sierra Bermeja, CRNWR, and GCF during the dry season.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with determining a species' listing status under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that there are no Tribal interests affected by this rule.

References Cited

A complete list of references cited is available on *https://www.regulations.gov* under Docket No. FWS–R4–ES–2019–0070.

Authors

The primary authors of this rule are members of the Caribbean Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.12, in paragraph (h), by revising the entry for ''*Eugenia woodburyana*'' under FLOWERING PLANTS in the List of Endangered and Threatened Plants to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
Flowering Plants				
*	*	*	*	* * *
Eugenia woodburyana	No common name	Wherever found	T	59 FR 46715, 9/9/1994; 87 FR [insert **Federal Register** page where the document begins], 12/2/2022; 50 CFR 17.73(e).[4d]
*	*	*	*	* * *

■ 3. Amend § 17.73 by adding paragraph (e) to read as follows:

§ 17.73 Special rules—flowering plants.

* * * * *

(e) *Eugenia woodburyana* (no common name).

(1) *Prohibitions.* The following prohibitions that apply to endangered plants also apply to *Eugenia woodburyana.* Except as provided under paragraph (e)(2) of this section, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.61(b) for endangered plants.

(ii) Remove and reduce to possession the species from areas under Federal jurisdiction, as set forth at § 17.61(c)(1) for endangered plants.

(iii) Maliciously damage or destroy the species on any areas under Federal jurisdiction, or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any law or regulation of the Territory or in the course of any violation of a Territorial criminal trespass law, as set forth at section 9(a)(2)(B) of the Act.

(iv) Engage in interstate or foreign commerce in the course of commercial activity, as set forth at § 17.61(d) for endangered plants.

(v) Sell or offer for sale in interstate or foreign commerce, as set forth at § 17.61(e) for endangered plants.

(2) *Exceptions from prohibitions.* The following exceptions from prohibitions apply to *Eugenia woodburyana:*

(i) The prohibitions described in paragraph (e)(1) of this section do not apply to activities conducted as authorized by a permit issued in accordance with the provisions set forth at § 17.72.

(ii) Any employee or agent of the Service or of a State or Territorial conservation agency that is operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, may, when acting in the course of official duties, remove and reduce to possession from areas under Federal jurisdiction members of *Eugenia woodburyana* that are covered by an approved cooperative agreement to carry out conservation programs.

(iii) Individuals may engage in any act prohibited under paragraph (e)(1) of this section with seeds of cultivated specimens, provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container.

* * * * *

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–25706 Filed 12–1–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 200124–0029; RTID 0648–XC582]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; 2023 Red Snapper Private Angling Component Closures in Federal Waters off Texas

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces a closure for the 2023 fishing season for the red snapper private angling component in the exclusive economic zone (EEZ) off Texas in the Gulf of Mexico (Gulf) through this temporary rule. The red snapper recreational private angling component in the Gulf EEZ off Texas will close on January 1, 2023, until 12:01 a.m., local time, on June 1, 2023. This closure is necessary to prevent the private angling component from exceeding the Texas regional management area annual catch limit (ACL) and to prevent overfishing of the Gulf red snapper resource.

DATES: This closure is effective at 12:01 a.m., local time, on January 1, 2023, until 12:01 a.m., local time, on June 1, 2023.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *Kelli.ODonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule implementing Amendment 40 to the FMP established two components within the recreational sector fishing for Gulf red snapper: the private angling component, and the Federal for-hire component (80 FR 22422, April 22, 2015). Amendment 40 also allocated the red snapper recreational ACL (recreational quota) between the components and established separate seasonal closures for the two components. On February 6, 2020, NMFS implemented Amendments 50 A–F to the FMP, which delegated authority to the Gulf states (Louisiana, Mississippi, Alabama, Florida, and Texas) to establish specific management measures for the harvest of red snapper in Federal waters of the Gulf by the private angling component of the recreational sector (85 FR 6819, February 6, 2020). These amendments allocate a portion of the private angling ACL to each state, and each state is required to constrain landings to its allocation.

As described at 50 CFR 622.23(c), a Gulf state with an active delegation may request that NMFS close all, or an area of, Federal waters off that state to the harvest and possession of red snapper by private anglers. The state is required to request the closure by letter to NMFS, providing dates and geographic coordinates for the closure. If the request is within the scope of the analysis in Amendment 50A, NMFS publishes a notice in the **Federal Register** implementing the closure for the fishing year. Based on the analysis in Amendment 50A, Texas may request a closure of all Federal waters off the State to allow a year-round fishing season in State waters. As described at 50 CFR 622.2, ''off Texas'' is defined as the waters in the Gulf west of a rhumb line from 29°32.1′ N lat., 93°47.7′ W long. to 26°11.4′ N lat., 92°53′ W long., which line is an extension of the boundary between Louisiana and Texas.

On November 21, 2022, NMFS received a request from the Texas Parks and Wildlife Department (TPWD) to close the EEZ off Texas to the red snapper private angling component during the 2023 fishing year. Texas requested that the closure be effective from January 1 through May 31, 2023. NMFS has determined that this request is within the scope of analysis contained within Amendment 50A, which analyzed the potential impacts of a closure of all Federal waters off Texas, consistent with Texas's intent to maintain a year-round fishing season in State waters during which a part of Texas' ACL could be caught.

Therefore, the red snapper recreational private angling component

in the Gulf EEZ off Texas will close at 12:01 a.m., local time, on January 1, 2023, until 12:01 a.m., local time, on June 1, 2023. This closure applies to all private-anglers (those on board vessels that have not been issued a valid charter vessel/headboat permit for Gulf reef fish) regardless of which state they are from or where they intend to land. Once the EEZ off Texas opens on June 1, 2023, TPWD will continue to monitor private recreational landings, and if necessary, will request that NMFS again close the EEZ in 2023 to ensure the Texas regional management area ACL is not exceeded.

On and after the effective dates of this closure in the EEZ off Texas, the harvest and possession red snapper in the EEZ off Texas by the private angling component is prohibited and the bag and possession limits for the red snapper private angling component in the closed area is zero.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.23(c), which was issued pursuant to 304(b), and is exempt from review under Executive Order 12866, and other applicable laws.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule implementing the area closure authority and the State-specific private angling ACLs has already been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because a failure to implement the closure immediately would be inconsistent with Texas's State management plan and may result in less access to red snapper in State waters.

For the aforementioned reasons, there is good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 29, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–26303 Filed 12–1–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 221122–0247]

RIN 0648–BL02

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Data Calibrations and Harvest Levels

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in two framework actions under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico (Gulf) Fishery Management Council (Council). This final rule modifies the state-specific red snapper private angling components annual catch limits (ACLs) to reflect each state's monitoring program. In addition, this final rule modifies commercial and recreational sector and recreational component red snapper ACLs and annual catch targets (ACTs) in the Gulf exclusive economic zone (EEZ). The purpose of this final rule is to calibrate Gulf red snapper state private angling component ACLs to reduce the likelihood of overfishing, to increase the Gulf red snapper ACLs and ACTs consistent with the best scientific information available, and to continue to achieve optimum yield (OY) for the stock.

DATES: This final rule is effective January 1, 2023.

ADDRESSES: Electronic copies of the framework actions, which include environmental assessments, regulatory impact reviews, and Regulatory Flexibility Act (RFA) analyses, may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/red-snapper-data-calibrations-and-catch-limit-modifications.*

FOR FURTHER INFORMATION CONTACT: Dan Luers, Southeast Regional Office, NMFS, telephone: 727–824–5305, email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the FMP. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Steven Act).

On June 28, 2022, NMFS published a proposed rule for the framework actions and requested public comment (87 FR 38366). The proposed rule and the framework actions outline the rationale for the actions contained in this final rule. A summary of the management measures described in the framework actions and implemented by this final rule is described below.

Unless otherwise noted, all weights in this final rule are in round weight.

This final rule implements management measures for both the Gulf of Mexico Red Snapper Recreational Data Calibration and Recreational Catch Limits Framework Action (Calibration Framework) and the Modification of Annual Catch Limits for Gulf of Mexico Red Snapper Framework Action (Catch Limits Framework). Briefly, the Calibration Framework modifies the state-specific red snapper private angling component ACLs using the calibration ratios developed by NMFS' Office of Science and Technology (OST) and the Gulf states. The Catch Limits Framework increases the red snapper overfishing limit (OFL), acceptable biological catch (ABC), ACLs, and ACTs consistent with the red snapper interim analyses and recommendations from the Council's Scientific and Statistical Committee (SSC). These two framework actions are combined in this single final rule because both actions adjust the red snapper catch limits.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and to achieve, on a continuing basis, the OY from federally managed fish stocks to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

Red snapper in the Gulf EEZ is harvested by both the commercial and recreational sectors. Each sector has its own ACL and associated management measures. The stock ACL is allocated 51 percent to the commercial sector and 49 percent to the recreational sector. The stock ACL for red snapper is equal to the ABC. The recreational ACL (quota) is divided between the Federal for-hire component (42.3 percent), which includes operators of federally permitted charter vessels and headboats (for-hire vessels), and the private

angling component (57.7 percent), which includes private anglers.

In February 2020, NMFS implemented state management of red snapper for the private angling component through Amendments 50 A–F to the FMP (85 FR 6819, February 6, 2020). Under state management, each state was allocated a portion of the red snapper private angling component ACL and was delegated the authority to set the private angling fishing season, bag limit, and size limit. These amendments also established an accountability measure that required any overage of a state's ACL to be deducted in the following year (*i.e.,* a payback provision).

The Calibration Framework

The Calibration Framework describes in detail the various data collection programs used to estimate red snapper landings by private anglers. Until recently (2014), NMFS provided the only estimates of private angler red snapper landings in all of the Gulf states, except Texas. Texas anglers have never participated in the NMFS recreational data collection survey. In 2014, Alabama and Louisiana, and in 2015, Florida and Mississippi, implemented state data collection programs to collect this private angler information. Each of these programs is unique and NMFS has observed differences (sometimes substantial) between Federal estimates of recreational catch and each state's own estimate. Specifically, the Alabama and Mississippi surveys tend to generate much lower landings estimates than the Federal survey.

The current red snapper catch limits (OFL, ABC, ACLs, and ACTs) are based, in part, on private-angling landings estimated using the Federal data collection system, and NMFS uses the estimates from the Federal survey to determine whether landings exceed the total recreational ACL (quota) and the stock OFL. However, each Gulf state manages the harvest by its private anglers using estimates from its own state data collection program. The Federal Marine Recreational Information Program (MRIP) based catch limits for Florida, Alabama, Mississippi, and Louisiana are not directly comparable to the landings estimates generated by each of those states, and the state estimates are not directly comparable to each other. In other words, each state is estimating landings in a different ''currency.'' Therefore, the NMFS OST worked with the Gulf States to develop calibration ratios so that each state's catch limit could be converted from the Federal ''currency'' to the currency in which each state monitors landings.

The current systems each state uses to manage private angling harvest have resulted in exceeding the total recreational ACL (quota) and the OFL. In 2018 and 2019, the private angling component ACL and recreational ACL were exceeded even though the Federal for-hire component landings did not exceed the for-hire component ACL. In 2019, total red snapper landings exceeded the OFL.

To address this issue, the Council developed the Calibration Framework and selected as preferred the alternative that uses the calibration ratios to adjust each state's ACL into the currency in which that state monitors landings. These ratios are: Alabama (0.4875); Florida (1.0602); Louisiana (1.06); Mississippi (0.3840); Texas (1.00). The MRIP-based ACLs are multiplied by the ratios to determine the state currency ACLs. The preferred alternative also included an implementation date of January 1, 2023. The Council concluded that this delay in implementation would afford the Gulf states and the NMFS OST an opportunity to resolve the differences in state-specific data collection programs and MRIP-Fishing Effort Survey (FES) (*e.g.,* scale and precision of catch estimates), as recommended by both the Council's SSC (during discussion at several SSC meetings) and a 2021 National Academy of Sciences report to Congress.

In February 2022, NMFS OST and the Gulf states participated in a workshop on the transition to the use of state survey catch data in Gulf fisheries. The purpose of the workshop was to agree on the elements of a transition plan for the Gulf state recreation fishing surveys. The transition plan was published in August 2022, and can be found at *https://media.fisheries.noaa.gov/2022-10/Gulf%20Transition%20Plan%20Final.pdf.*

The Catch Limits Framework

In 2019, NMFS implemented a framework action that set the current red snapper catch limits (85 FR 6819, February 6, 2020). These catch limits are based on most recent Gulf red snapper Southeast Data, Assessment, and Review stock assessment (SEDAR 52), completed in 2018, and the Council's SSC recommendations. The current red snapper stock OFL is 15.5 million lb (7.0 million kg), the stock ABC and stock ACL are 15.1 million lb (6.8 million kg). The commercial ACL is 7.701 million lb (3.493 million kg), and the recreational ACL is 7.399 million lb (3.356 million kg). The Federal for-hire component ACL is 3.130 million lb (1.420 million kg) and the private angling component ACL is 4.269 million lb (1.936 million kg). The Federal for-hire component ACT is 2.848 million lb (1.292 million kg) and the private angling component ACT is 3.415 million lb (1.5498 million kg). The commercial sector does not have a sector ACT because it is managed under an individual fishing quota (IFQ) program that effectively constrains landings to the commercial ACL. The 2019 framework also set the Federal for-hire component ACT at 9 percent below its ACL. The for-hire component ACT is in place to reduce the likelihood of exceeding the for-hire ACL, as well as the total recreational ACL. A private angling component ACT is set 20 percent below the private angling ACL, but would only be used if a Gulf state did not have an active delegation under the red snapper state management program.

In 2016, Congress awarded funding to researchers in an effort to independently estimate the population size of red snapper in the Gulf. Commonly known as the ''Great Red Snapper Count'' (GRSC), this project's primary goal was to provide a snapshot of estimate abundance and distribution of age 2 and older red snapper on artificial, natural, and uncharacterized bottom habitat across the northern Gulf through 2019. At its April 2021 meeting, the Council was briefed on the preliminary results of the GRSC. The GRSC estimated the abundance of red snapper in the Northern Gulf was approximately three times greater than had been estimated in the previous stock assessment (SEDAR 52).

The Southeast Fisheries Science Center (SEFSC) worked collaboratively with the GRSC investigators to develop a method that could be used to integrate the results of the GRSC into catch limit advice that is currently based on SEDAR 52. The SEFSC developed catch projections using GRSC estimates of abundance to scale projections that initially used abundance estimates from SEDAR 52. The SEFSC also developed catch level projections based on an interim analysis using information from the NMFS Bottom Longline (BLL) survey from 2000 through 2020, which was similar to the approach previously used for Gulf red grouper and gray triggerfish projections. The NMFS BLL survey is an annual survey that can be used to determine long-term trends in the abundance of a stock.

The SSC reviewed both sets of projections at its March 30–April 2, 2021, meeting. The SSC expressed some concerns about using the GRSC findings to recommend catch levels. Specifically,

the SSC noted the uncertainty associated with the GRSC biomass estimate, questions about the productivity of the red snapper stock that are raised by the GRSC findings (that the productivity of the stock appears to be lower than previously assumed), and the declining trend observed recently in the NMFS BLL survey. Based on these concerns, and until additional information could be presented related to the SSC's questions about some aspects of the GRSC, the SSC determined that it was appropriate to use the GRSC based interim analysis to recommend the OFL, which would be used determine if overfishing is occurring, but not to use the GRSC to recommend the ABC, which constrains the total allowable catch that may be specified by the Council.

For the OFL recommendation, the SSC decided to use the projection based on the abundance of all red snapper over structure (artificial reef, natural reef, and pipeline) and 13 percent of the abundance from the unclassified bottom, and used a 3-year average of the maximum sustainable yield proxy for Gulf red snapper (the mortality corresponding to a 26 percent reduction in the spawning potential ratio from an unfished condition). This OFL for Gulf red snapper is 25.6 million lb (11.6 million kg). With respect to the ABC, the SSC determined that 2020 BLL survey data should not be used for this interim analysis because of the low sample size and high coefficient of variation for those data that were likely the result of the COVID–19 pandemic, and recommended that the catch advice be derived from the 5-year average. Based on these selections, the Council's SSC provided an ABC recommendation for Gulf red snapper of 15.4 million lb (7.0 million kg). This recommendation reflects the SSC's determination that the ABC should be considerably more conservative than the OFL, at least until the SSC questions related to the GRSC are more thoroughly explored.

The SSC has reviewed new information related the GRSC on several occasions, including at its March 2022 meeting. At that same meeting, the SEFSC presented an analysis that used the updated GRSC information, and the SSC made new catch level recommendations based on this new analysis. These new recommendations decrease the OFL to 18.91 million lb (8.58 million kg) and increase the ABC to 16.31 million lb (7.40 million kg). In August 2022, the Council finalized a new framework action to adjust the red snapper catch limits consistent with these recommendations. In October 2022, the Council submitted the new framework action and proposed regulations to NMFS for review.

The Council approved both the Data Calibration Framework Action and the Catch Limits Framework Action at its April 2021 meeting. However, NMFS expressed concern about the Council's proposal to delay implementation of the Calibration Framework until 2023, and requested that the Council reconsider that implementation timing. The Council discussed the request at its August 2021 meeting but did not make any changes to the implementation date of the preferred alternative.

Management Measures Contained in This Final Rule

This final rule modifies the state-specific red snapper private angling component ACLs using the calibration ratios adopted by the Council, and increases the red snapper ACLs and ACTs consistent with the red snapper interim analyses and the subsequent SSC recommendations. The calibrations are necessary to convert the state private angling component ACLs into the same currency in which each state monitors landings by the private angling component. This will reduce the likelihood of exceeding the red snapper private angling component ACL, the total recreational ACL, and the OFL.

ACLs and ACTs

This final rule increases the Gulf red snapper catch limits. The stock ACL will increase from 15,100,000 lb (6,800,000 kg) to 15,400,000 lb (7,000,000 million kg). The commercial ACL (commercial quota) will increase from 7,701,000 lb (3,493,000 kg) to 7,854,000 lb (3,562,514 kg), and the recreational ACL (recreational quota) will increase from 7,399,000 lb (3,356,000 kg) to 7,546,000 lb (3,422,808 kg). The for-hire component recreational ACL will increase from 3,130,000 lb (1,420,000 kg) to 3,191,958 lb (1,447,848 kg). The private angling component recreational ACL will increase from 4,269,000 lb (1,936,000 kg) to 4,354,042 lb (1,974,960 kg). In addition, the private angling recreational ACT will increase from 3,415,000 lb (1,549,000 million kg kg) to 3,483,234 lb (1,579,968 kg).

For the Federal for-hire component, the Council chose to maintain the current buffer between the ACL and ACT at 9 percent to minimize the risk of ACL overages. Therefore, as a result, the for-hire component ACT will increase from 2,848,000 lb (1,292,000 kg) to 2,904,682 lb (1,317,542 kg).

Because of the increased recreational private angling component ACL in this final rule, each Gulf state will be initially allocated an increase in their specific state private angling component ACL. Alabama's ACL will increase from 1,122,662 lb (509,231 kg) to 1,145,026 lb (519,375 kg); Florida's ACL will increase from 1,913,451 lb (867,927 kg) to 1,951,569 lb (885,217 kg); Louisiana's ACL will increase from 816,233 lb (370,237 kg) to 832,493 lb (377,612 kg); Mississippi's ACL will increase from 151,550 lb (68,742 kg) to 154,568 lb (70,110 kg); and Texas's ACL will increase from 265,105 lb (120,250 kg) to 270,386 lb (122,645 kg). The above changes to individual state catch limits are based on the Catch Limits Framework. These are not the final catch limits that will be implemented through this final rule and they are not included in the codified text in this rule because the calibration ratios need to be applied as described in the following paragraph.

Each Gulf state's private angling component ACL denoted in the prior paragraph was modified by applying the calibration ratios adopted by the Council. The final private angling component ACLs followed by the Federal equivalent are as follows: the Alabama private angling component ACL will be 558,200 lb (253,195 kg) or Federal equivalent of 1,145,026 lb (519,375 kg); the Florida private angling component ACL will be 2,069,053 lb (938,507 kg) or Federal equivalent of 1,951,569 lb (885,217 kg); the Louisiana private angling component ACL will be 882,443 lb (400,269 kg) or Federal equivalent of 832,493 lb (337,612 kg); the Mississippi private angling component ACL will be 59,354 lb (26,923 kg) or Federal equivalent of 154,568 lb (70,111 kg); and the Texas private angling component ACL (equal to Federal) will be 270,386 lb (122,645 kg). Each state will use its reporting system to monitoring landings and appropriately constrain harvest to its ACL. NMFS will convert the state landings estimates to the Federal currency to determine whether landings have been constrained to the private angling ACL, total recreational ACL (quota) and OFL. This is necessary because the private angling ACL, total recreational ACL (quota) and OFL will remain in the Federal currency.

Minority Report

A minority report signed by three Council members raised objections to the Council's decision to approve the Calibration Framework with an implementation date of January 1, 2023, included in the preferred alternative. These Council members were concerned that delaying implementation until 2023 would allow 2 additional fishing years

(2021 and 2022) where the private angling component of the recreational sector would be allowed to catch more than its allocation of red snapper. The minority report is available at the website: *https://gulfcouncil.org/wp-content/uploads/Council-Minority-Report-FINAL-Signatures.pdf.*

Comments and Responses

NMFS received 39 comments on the proposed rule, including one comment that contained signed letters as part of a petition. The petition, which is in favor of the Calibration Framework, had 7,351 individual signatures. In general, commercial fishermen and environmental non-government organizations supported the calibration action. Overall, 16 comments were received in support of the Calibration Framework (including the petitioners above) and 16 were opposed. Two commenters supported the calibration action but did not support the catch limit increase. Several additional comments were received on topics that are outside the scope of the proposed rule and framework actions. These included comments addressing state management issues, allocation decisions and the suggestion that the Council initiate an allocation review for red snapper, issues about the red snapper commercial fishery, recreational bag limit changes, the composition of the Gulf Council, and recreational discard accounting.

Comments specific to the framework actions and the proposed rule are grouped as appropriate and summarized below, each followed by NMFS' respective response.

Comment 1: NMFS should implement the calibration ratios as proposed without further delay as recommended in the Council's minority report. The lack of calibration has masked large recreational overharvests. The private angling component of the recreational sector exceeded its quota from 2018–2021 by a total of more than 4.1 million lb (1.9 million kg), resulting in the overall recreational sector exceeding its quota by more than 2 million lb (0.9 million kg) over the same time period. Those quota overages have not been paid back as required. Calibration to a ''common currency'' is necessary to comply with the Magnuson-Stevens Act.

Response: NMFS agrees that red snapper calibration ratios are needed and they will be implemented along with the catch limit increases through this final rule. These changes will be effective January 1, 2023. It is unlikely that the rule could be made effective for the 2022 fishing year. Further, the Gulf States set their 2022 management measures based on the ACLs that have been in effect since the beginning of the year. Applying the calibration ratios and adjusting those ACLs at the end of the year does not provide the opportunity for the states to adjust their management strategies.

NMFS has been forthcoming about the different estimates produced by the Gulf State surveys and MRIP, and recognizes that the lack of the calibrated state ACLs has allowed the combined catch from the Gulf States to exceed the private angling component ACL. NMFS expects the calibrated state ACLS implemented through this final rule to help constrain harvest to the Federal catch limits established in Amendments 50A–F and increased through this final rule, and reduce the likelihood of exceeding the total recreational ACL and the OFL.

With respect to the payback of prior overages, this requirement was adopted to encourage each state to adopt management measures that constrain harvest to the state ACL. When state reported landings have exceeded the codified state ACLs, NMFS has implemented paybacks to address the overages for: Texas in 2020 and 2021 (for overages of their ACL in 2019 and 2020), Louisiana in 2020 and 2022 (overages in 2019 and 2021), and Florida in 2022 (overage in 2021). NMFS has not implemented paybacks for Mississippi or Alabama because landings estimates provided by these states have not exceeded their codified ACLs. The calibrated state ACLs implemented through this final rule will allow NMFS to directly compare each state's landings estimate to its ACL and implement any necessary payback.

Comment 2: The MRIP data are flawed and the calibration ratios should not be considered best scientific information available for that reason. Additionally, NMFS is not using the best scientific information available to set catch limits as described in the Catch Limits Framework because the SSC provided the Council with new OFL and ABC recommendations.

Response: NMFS has determined that both the calibration ratios and catch limit modifications as described in the framework actions and this final rule are based on the best scientific information available as required by National Standard 2 of the Magnuson-Stevens Act. The Federal surveys have been heavily tested, scrutinized, and reviewed, and NMFS remains committed to continue improving both state and Federal survey methods, all of which are subject to sampling and non-sampling errors (measurement, coverage, and non-response). MRIP uses standardized designs across states, which ensures comparability of estimates. Conversely, due to the differing designs by the Gulf States, it is not possible to directly compare the estimates derived from the state surveys to each other or to the estimates produced by MRIP. The state ACLs were derived, in part, based on private-angling landings estimated using MRIP. Applying the state specific calibration ratio to each state's MRIP-based ACL will allow each state's landings estimate to be compared directly that state's ACL.

The calibration ratios were developed in partnership with experts from the Gulf States and reviewed by a team of independent experts and the Gulf Council's SSC. The catch limit increase is based on interim analyses conducted by the SEFSC and the recommendation of the SSC. The SEFSC has since conducted a new interim analysis and the SSC has made new catch level recommendations, which the Council adopted in a subsequent framework action. NMFS is reviewing the proposed regulations associated with the new framework action and will publish a proposed rule to implement those regulations if NMFS determines that they are consistent with the FMP, the Magnuson-Stevens Act, and other applicable law.

Comment 3: Alabama and Mississippi have better programs in place to estimate red snapper recreational catch than MRIP, and NMFS does a poor job of tracking red snapper recreational catch. For example, the Mississippi ''Tails n' Scales'' recreational reporting program, when compared to MRIP, has a greater response rate, is more accurate, has a lower standard error, has less fluctuations of harvest estimates across years, and is more consistent across seasons and years. Alabama and Mississippi's catch reporting programs suggest the rest of the Gulf States are actually overestimating red snapper recreational catch.

Response: NMFS agrees that the Alabama and Mississippi surveys tend to generate much lower landings estimates than the Federal survey, and that the Alabama Snapper Check and the Mississippi Tails n' Scales programs are designed to produce more precise and timely estimates of catch. However, because the state ACLs were derived using Federal estimates of recreational catch, calibrations are needed to convert the state ACLs to the same scale that each state uses to monitor landings. Stated differently, because the Alabama and Mississippi surveys produce lower estimates of landings than the survey used to set those state's ACLs, anglers from Alabama and Mississippi have been allowed to land more red snapper

than contemplated by the Council when developing Amendments 50A–F.

In addition, the fact that the Alabama and Mississippi surveys result in lower estimates than MRIP does not necessarily mean that the other states are overestimating landings. It is difficult to know which surveys provide the best estimates of catch. Different statistical sampling designs can produce different estimates due to variations in sampling frames and non-sampling error such as coverage error, nonresponse error, and measurement error. It is not unusual for established surveys to produce very different estimates for the same population parameter. NMFS explained the different state surveys, including key survey design assumptions and potential for bias in the 2019 publication, ''Recommended Use of the Current Gulf of Mexico Surveys of Marine Recreational Fishing in Stock Assessments,'' available at *https://media.fisheries.noaa.gov/dam-migration/94100569.pdf.* The Transition Plan for Gulf State Recreational Fishing Surveys includes a research track to identify and quantify non-sampling errors in survey designs of all participating partner programs and may lead to design improvements in those assessments to reduce non-sampling errors and the magnitude of differences in catch estimates among the unique data programs.

Comment 4: While calibration is necessary, MRIP should not be used for estimating recreational landings in the Gulf because it was not designed to generate estimates on a smaller geographic scale (*e.g.,* the 44 miles (71 km) of Mississippi coastline) and for shorter periods of time. Therefore, this rule is arbitrary and capricious because it relies on flawed data to cut Mississippi's recreational red snapper private angling allowable harvest by 60 percent.

Response: NMFS disagrees that MRIP should not be used to estimate recreational landings in the Gulf. Until 2014, MRIP, and its predecessor the Marine Recreational Fisheries Statistics Survey (MRFSS), were the only surveys available to estimate private angler red snapper landings in all of the Gulf States, except Texas. MRIP remains the only survey available to estimate private angler landings of many other federal managed species. For example, reporting to the Mississippi Tails n' Scales program is only required for recreational anglers fishing for red snapper, although anglers are also asked to report data on gray triggerfish and greater amberjack. NMFS has determined that the calibrations implemented through this final rule are not arbitrary and capricious. For the reasons explained previously, the calibrations are necessary to allow each state's landings estimates to be directly compared to its ACL.

Comment 5: Many states do not use the Federal survey to estimate recreational landings. States with more resources, such as California, Oregon, and Washington, transitioned away from the Federal survey without undergoing calibration. In the Gulf, Texas never participated in the Federal survey program and is allowed simply to continue using its state data to comply with Amendment 50, and Louisiana stopped participating in MRIP in 2016. This does not seem fair to the other Gulf States.

Response: California, Oregon, and Washington discontinued the Federal survey in 2004 prior to the first National Academy of Sciences review and the establishment of MRIP. At that time, Oregon and Washington had been conducting their own surveys for a number of years and were using MRFSS estimates to supplement those surveys. Further, NMFS did not have policies and procedures related to certification of new recreational catch and effort survey designs. California, Oregon, and Washington receive Federal funding through MRIP to support the state-conducted surveys and are currently going through MRIP certification reviews, consistent with NMFS Procedure 04–114–02 found at *https://media.fisheries.noaa.gov/2021-06/04-114-02_06.28.2021_Howell%20signed.pdf?null.* A requirement of certification is a transition plan, which will identify if there is a need for calibration.

With respect to the Gulf States, all of the states who participate in MRIP are being treated similarly with respect to calibrating their state specific red snapper ACLs. Texas has never participated in the Federal survey to estimate catch, using the Texas Coastal Creel Survey for more than 40 years. Because the implementation of Amendments 50A–F did not change the way in which Texas landings are monitored, no calibration of the Texas ACL is necessary. Only Louisiana ceased to conduct the Federal surveys since MRIP was established in 2008. But Louisiana continues to receive funding from MRIP and to participate on MRIP teams, and this final rule applies the appropriate calibration ratio to Louisiana's red snapper ACL.

Comment 6: NMFS should proceed with caution and perform further analysis before moving forward with the catch limit increases. The proposed increase in ACLs and ACTs are coming at a time when a large number of data sources are indicating that the stock is experiencing a decline in abundance and localized depletion.

Response: NMFS understands there are concerns about the status of the stock, and localized depletion in particular. However, NMFS does not agree that it is appropriate to delay the increase in the catch limits, which is based on new information from the GRSC and the NMFS BLL survey, and the recommendations of the Council's SSC. A new stock assessment for Gulf red snapper is underway and expected to be complete in 2024. The new assessment includes a research track component that is used to build a robust assessment tool and an operational component that provide analyses to support management advice with up-to-date data. NMFS expects the results of this new assessment to provide more information about the status of the red snapper stock, including whether there has been a decline in abundance. After the assessment is complete, it will be reviewed by the SSC and the Council will consider any appropriate changes to the catch limits or other management measures.

Comment 7: The two states most disadvantaged by this final rule, Mississippi and Alabama, have the lowest per capita income among the Gulf States and this should have been taken into account in developing the calibrations.

Response: NMFS does not have per capita or household income data for anglers that target or catch red snapper, in particular, and therefore cannot determine whether anglers in Mississippi and Alabama affected by this final rule are more disadvantaged than those in other Gulf States. NMFS does not believe that it would have been appropriate to consider this type of information in developing the calibrations, which are designed to allow a direct comparison between each state's estimated private angling red snapper landings and that state's private angling component ACL. To achieve that goal, the calibrations are based on how the catch estimates by the states compared to the Federal catch estimates, and did not differentiate between the states based on any other factors.

Comment 8: NMFS did not use appropriate methods to calibrate MRIP recreational data to state data. NMFS used the Fay-Herriot model to calibrate MRIP–CHTS data to MRIP–FES, and should have used a similar model to calibrate the state data to MRIP data. Instead, NMFS decided to use a simple linear calibration.

Response: NMFS disagrees that it was inappropriate to use a linear calibration to adjust the state ACLs to be comparable with the method each state uses to estimate landings. The Fay-Herriot model used for the CHTS to FES calibration was specifically developed for that purpose and cannot be applied as designed to provide calibrations among the various survey designs that states in the Gulf employ. Given the limited data available and need to develop the calibrations in a timely manner, NMFS and the Gulf states agreed that the simple ratio-based approach should be used until it could be updated or replaced when additional data become available.

Comment 9: The calibration for Mississippi should have included 2020 data rather than only 2018 and 2019 data. NMFS has informally suggested that 2020 MRIP data should not be considered because pandemic-related disruptions resulted in some missing data. However, NMFS used imputation, a statistically valid method which replaces missing data with substituted values, to compensate for the missing data, which created a usable landings estimates. Moreover, the percent standard error for 2020 data is consistent with other years, suggesting the data should be included. Inclusion of 2020 data for Mississippi would have been statistically more robust, and would have resulted in an increase in Mississippi's quota.

Response: NMFS disagrees that 2020 data should be used to revise the calibration ratio for Mississippi in this final rule. This data was not available when the calibration ratios were developed during the 2020 workshop or when the Council approved the Calibration Framework in April 2021. Any changes to the calibration ratios should be made through the Council process. In June 2022, the Council directed its SSC to review the calibration ratios using more recent state survey data and provide recommendations prior to the January 2023 Council meeting. NMFS is working with the Gulf states to update the calibration ratios, as appropriate, for review by the SSC at its January 2023 meeting. The Council can act to make any appropriate changes to the calibration ratios after the SSC presents its recommendations.

Comment 10: The Council's SSC recognized the shortcoming of the calibration and realized that Mississippi was being treated unfairly. In the minutes from the Council's SSC meeting of August 11–12, 2020, it states ''The SSC recognized that the difference in methodology by the state and Federal surveys should be explored further, as to not penalize a state when the difference after calibration greatly reduce the state's quota.'' This is exactly what was done with Mississippi. The Council's SSC minutes also state ''the SSC also agreed that scaling a state's data to MRIP–FES is not the same as calibrating those data, and that scaling to MRIPFES is tantamount to using the MRIP–FES data.'' Thus, the Council's SSC agreed that the Calibration Framework improperly dismissed nearly comprehensive data from the Mississippi Tails n' Scales program in favor of management using less appropriate MRIP–FES data.

Response: NMFS agrees that the Council's SSC has recognized shortcomings with the calibration ratios but does not agree that the SSC concluded that Mississippi was being treated unfairly or that the Calibration Framework improperly dismissed the Mississippi data. The SSC determined the methods used to generate conversion ratios between Gulf state surveys and MRIP data were appropriate for quota monitoring of the red snapper state specific ACLs. Those methods were developed in partnership with the Gulf states, including Mississippi, and with the input of independent statistical consultants.

Comment 11: Nearly 2 years ago, Congress appropriated $2 million for NMFS to work on the calibration issue, and the issue still has not been adequately addressed. Calibration was delayed to 2023 to find more effective ways to incorporate state data, but no changes were made to the calibration ratios. NMFS is ignoring explicit instructions from Congress to make no regulatory changes until it is determined which data estimation system (MRIP or state) is best.

Response: NMFS is not ignoring explicit instructions from Congress. Regardless of which surveys are determined to be ''best,'' the current state ACLs were developed using MRIP estimates while the state surveys monitor harvest using different methods. The Mississippi and Alabama surveys produce significantly lower estimates of catch, and ignoring those differences has resulted in the private angling component exceeding its ACL and could result in overfishing of red snapper. Therefore, NMFS is implementing the calibration ratios consistent with the requirements of the Magnuson-Stevens Act. NMFS recognized the need to calibrate the state ACLs to each state's reporting system in the final rule implementing state management of red snapper. The calibration ratios were adopted by the Gulf Council after a fully transparent process that included thorough Council and SSC deliberation, coordination with the Gulf States, peer review, and extensive opportunity for public comment. Appropriations from Congress were used to work with the Gulf States to review the state and Federal surveys, look at possible improvements, identify how to make those improvements, and complete a review of an updated calibration methodology. In February 2022, NMFS, its state partners, and a team of independent experts participated in a workshop to make the decisions necessary to develop a multi-year transition plan to support the use of Gulf state recreational fishing data in Federal stock assessments and management decisions. This plan includes two parallel paths, a transition path and a research path, with both short and long-term priorities. In the short-term, the transition path will make immediate progress on interim calibration of historical catch estimates using currently available data and ratio-based calibration methods. Long-term, as progress is made on the research path, the transition path will convene an independent review of model-based calibration procedures. This transition plan can be found at *https://media.fisheries.noaa.gov/2022-10/Gulf%20Transition%20Plan%20Final.pdf.*

NMFS acknowledges that when using MRIP that the general surveys may not meet some regional needs. To help meet those needs, regional implementation teams were established for MRIP to focus on the development of regional implementation plans in which data collection needs are described. Further, a goal of the development of state-specific surveys was to address the need for more timely and precise catch estimates to support short-season fisheries. NMFS has supported the testing and implementation of these surveys and continues to do so. Part of the transition plan for the Gulf surveys is focused on research needs to identify sources of non-sampling error so that improvements can be made to the surveys to better position them for an independent review of calibration methods and make recommendations on calibration.

Comment 12: This final rule is not based on accurate science and ignores the Magnuson-Stevens Act's explicit instruction to achieve OY because NMFS and the Council are ignoring the GRSC in developing the proposed ACLs. Specifically, the GRSC found that there are approximately three times more fish than was previously thought. Before the

GRSC, the stock ACL was set 3 percent below the OFL. Now that NMFS knows there are three times more fish than previously thought, the proposed stock ACL is set 40 percent below the OFL and was based on data from the non-targeted NMFS BLL sampling instead of the superior GRSC.

Response: NMFS disagrees that the catch limits implemented through this final rule are inconsistent with the requirements of the Magnuson-Sevens Act by ignoring the results of the GRSC. The stock ACL is equal to the ABC and the buffer between the OFL and ABC is intended to account for scientific uncertainty. The SEFSC developed catch projections using GRSC estimates of abundance to scale projections that initially used abundance estimates from the most recent stock assessment (SEDAR 52). The SEFSC also developed catch level projections based on an interim analysis that used information from the NMFS BLL survey, which was similar to the approach previously used for Gulf red grouper and gray triggerfish projections. The BLL survey is specifically designed to collect data for indices of abundance for snappers (including red snapper), groupers, and other species. The Council's SSC reviewed both sets of projections at its March 30 to April 2, 2021, meeting and determined that it was appropriate to use the GRSC-based interim analysis to specify the OFL at 25.6 million lb (11.6 million kg). Despite the groundbreaking advances of the GRSC, the Council's SSC identified some limitations and caveats of the study that they concluded warranted further investigation and consideration when determining the applicability of this information to inform catch level recommendations. Thus, the Council's SSC did not make an ABC recommendation based on the GRSC-informed interim analysis, but instead used the BLL interim analysis and provided an ABC recommendation of 15.4 million lb (7.0 million kg). As explained in response to *Comment 2,* NMFS is currently reviewing proposed regulations submitted by the Council that would decrease the OFL but increase the ABC. These proposed regulations are based on new SSC recommendations after reviewing updated GRSC information, and would set the stock ACL 14 percent below the OFL.

Comment 13: NMFS has already certified the state recreational data collection programs, including those in Mississippi and Alabama, so why is calibration required for those states.

Response: Through the MRIP peer review process, NMFS has certified various state survey designs as statistically valid with some critical assumptions. However, different certified survey designs, with different critical assumptions, can produce consistently different catch estimates. The calibrations are necessary to reconcile differences between two sets of estimates and allow for a direct comparison between each state's ACL and the landings estimates produced by that state's survey.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the framework actions, the FMP, other provisions of the Magnuson-Stevens Act, and other applicable laws.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the legal basis for this final rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule. This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995. A description of this final rule, why it is being considered, and the purposes of this final rule are contained in the preamble and in the **SUMMARY** section of this final rule.

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. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

List of Subjects in 50 CFR Part 622

Annual catch limits, Fisheries, Fishing, Gulf, Red snapper, Reef fish, Quota.

Dated: November 22, 2022.

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 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.23, revise paragraph (a)(1)(ii) to read as follows:

§ 622.23 State management of the red snapper recreational sector private angling component in the Gulf EEZ.

(a) * * *

(1) * * *

(ii) *State private angling component ACLs.* All ACLs specified below are in round weight and are consistent with monitoring under the respective state's reporting system. Equivalent ACLs, consistent with monitoring under the Federal reporting system, are provided, as applicable. If a state's delegation is suspended, as described in paragraph (a)(1) of this section, the Federal equivalent ACL, or for the Texas regional management area the ACL in paragraph (a)(1)(ii)(E) of this section, applies in the EEZ off that state.

(A) *Alabama regional management area*—558,200 lb (253,195 kg); Federal equivalent—1,145,026 lb (519,375 kg).

(B) *Florida regional management area*—2,069,053 lb (938,507 kg); Federal equivalent—1,951,569 lb (885,217 kg).

(C) *Louisiana regional management area*—882,443 lb (400,269 kg); Federal equivalent—832,493 lb (337,612 kg).

(D) *Mississippi regional management area*—59,354 lb (26,923 kg); Federal equivalent—154,568 lb (70,111 kg).

(E) *Texas regional management area*—270,386 lb (122,645 kg).

* * * * *

■ 3. In § 622.39, revise paragraphs (a)(1)(i) and (a)(2)(i) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(i) Commercial quota for red snapper—7,854,000 lb (3,562,514 kg), round weight.

* * * * *

(2) * * *

(i) *Recreational quota for red snapper*—(A) *Total recreational.* The total recreational quota is 7,546,000 lb (3,422,808 kg), round weight.

(B) *Federal charter vessel/headboat component quota.* The Federal charter vessel/headboat component quota applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. A person aboard a vessel that has been issued a charter

vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf EEZ when the Federal charter vessel/headboat component is closed. The Federal charter vessel/headboat component quota is 3,191,958 lb (1,447,848 kg), round weight.

(C) *Private angling component quota.* The private angling component quota applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. The private angling component quota is 4,354,042 lb (1,974,960 kg), round weight.

* * * * *

■ 4. In § 622.41, revise the last sentence in paragraphs (q)(2)(iii)(B) and (q)(2)(iii)(C) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(q) * * *

(2) * * *

(iii) * * *

(B) * * * The component ACT is 2,904,682 lb (1,317,542 kg), round weight.

(C) * * * The component ACT is 3,483,234 lb (1,579,968 kg), round weight.

[FR Doc. 2022–26019 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 220126–0034]

RTID 0648–XC554

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfers From ME to RI

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

ACTION: Notification; quota transfer.

SUMMARY: NMFS announces that the State of Maine is transferring a portion of its 2022 commercial bluefish quota to the State of Rhode Island. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Maine and Rhode Island.

DATES: Effective December 1, 2022, through December 31, 2022.

FOR FURTHER INFORMATION CONTACT: Laura Deighan, Fishery Management Specialist, (978) 281–9184.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2022 allocations were published on February 2, 2022 (87 FR 5739).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan (FMP) published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must approve any such transfer based on the criteria in § 648.162(e). In evaluating requests to transfer a quota or combine quotas, the Regional Administrator shall consider whether: The transfer or combinations would preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Act.

Maine is transferring 15,000 lb (6,804 kg) to Rhode Island through mutual agreement of the states. This transfer was requested to ensure Rhode Island would not exceed its 2022 state quota. The revised bluefish quotas for 2022 are: Maine, 5,819 lb (2,639 kg) and Rhode Island, 339,956 lb (154,201 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 28, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–26236 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 211217–0262; RTID 0648–XC575]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From VA to RI

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

ACTION: Notification of quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2022 commercial summer flounder quota to the State of Rhode Island. This adjustment to the 2022 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised 2022 commercial quotas for Virginia and Rhode Island.

DATES: Effective December 1, 2022, through December 31, 2022.

FOR FURTHER INFORMATION CONTACT: Laura Deighan, Fishery Management Specialist, (978) 281–9184.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.110. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102 and final 2022 allocations were published on December 23, 2021 (86 FR 72859).

The final rule implementing Amendment 5 to the Summer Flounder Fishery Management Plan (FMP), as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: The transfer or

combinations would not preclude the overall annual quota from being fully harvested; the transfer addresses an unforeseen variation or contingency in the fishery; and the transfer is consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act. The Regional Administrator has determined these three criteria have been met for the transfer approved in this notification.

Virginia is transferring 10,375 lb (4,706 kg) to Rhode Island through mutual agreement of the states. This transfer was requested to repay landings made by an out-of-state permitted vessel under a safe harbor agreement. The revised summer flounder quotas for 2022 are: Virginia, 2,786,216 lb (1,268,806 kg) and Rhode Island, 2,254,702 lb (1,022,716 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 29, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–26287 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 220223–0054; RTID 0648–XC381]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the Eastern Aleutian district (EAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2022 total allowable catch (TAC) of Pacific ocean perch in the EAI allocated to vessels participating in the BSAI trawl limited access sector fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 29, 2022, through 2400 hrs, A.l.t., December 31, 2022.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan (FMP) for Groundfish of the BSAI prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the BSAI FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2022 TAC of Pacific ocean perch, in the EAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 712 metric tons by the final 2022 and 2023 harvest specifications for groundfish in the BSAI (87 FR 11626, March 2, 2022).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the EAI by vessels participating in the BSAI trawl limited access sector fishery. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific ocean perch directed fishery in the EAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 28, 2022.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 29, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–26273 Filed 11–29–22; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 231
Friday, December 2, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 429 and 431

[EERE–2022–BT–TP–0003]

RIN 1904–AE95

Energy Conservation Program: Test Procedure for Dedicated-Purpose Pool Pumps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking and announcement of public meeting.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes to amend the test procedures for dedicated-purpose pool pumps (''DPPPs'') to incorporate by reference the latest version of the relevant industry standards, to codify DOE's current enforcement policy regarding the scope of the DPPP test procedure pertaining to DPPPs that cannot be appropriately tested by the current DOE test procedure, to align DOE's DPPP definitions with DOE's corresponding DPPP motor definitions, and to remove an obsolete DOE DPPP test procedure appendix. DOE is seeking comment from interested parties on the proposal.

DATES: DOE will accept comments, data, and information regarding this proposal no later than January 31, 2023. See section V, ''Public Participation,'' for details.

DOE will hold a public meeting via webinar on Monday, December 12, 2022, from 1:00 p.m. to 4:00 p.m. See section V, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov,* under docket number EERE–2022–BT–TP–0003. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2022–BT–TP–0003, by any of the following methods:

Email: DPPP2022tp0003@ee.doe.gov. Include the docket number EERE–2022–BT–TP–0003 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section V of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at *www.regulations.gov*. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2022-BT-TP-0003*. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Mr. Nolan Brickwood, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–4498. Email: *nolan.brickwood@hq.doe.gov*.

For further information on how to submit a comment, review other public comments and the docket, or participate in a public meeting (if one is held), contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

SUPPLEMENTARY INFORMATION: DOE proposes to incorporate by reference the following industry standards into 10 CFR part 431:

CSA C747–2009 (Reaffirmed 2019), ''Energy efficiency test methods for small motors,'' CSA reaffirmed 2019, (''CSA C747–09 (R2019)'').

HI 40.6–2021, ''Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing'', approved February 17, 2021.

NSF/ANSI/CAN 50–2020, ''Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities,'' designated as an ANSI Standard and National Standard of Canada October 21, 2020.

Copies of CSA C747–2009 are available at *www.csagroup.org*.

Copies of HI 40.6–2021 are available at *www.pumps.org*.

Copies of NSF/ANSI/CAN 50–2020 are available at *www.ansi.org* or *www.scc.ca/en/welcome-standards-store*.

See section IV.M of this document for a further discussion of these standards.

Table of Contents

I. Authority and Background

A dedicated-purpose pool pump is a type of ''pump.'' Pumps are included in the list of ''covered equipment'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6311(1)(A)) DOE's energy conservation standards and test procedures for DPPPs are currently prescribed at title 10 of the Code of Federal Regulations (''CFR''), § 431.464(b), and appendices B and C to subpart Y of part 431. The following sections discuss DOE's authority to establish test procedures for DPPPs and relevant background information regarding DOE's consideration of test procedures for this equipment.

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of several consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA, added by Public Law 95–619, Title IV, section 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. ''Pumps'' are listed as a type of industrial equipment covered by EPCA, although EPCA does not define the term ''pump.'' (42 U.S.C. 6311(1)(A)) DOE has defined ''pump'' as equipment designed to move liquids (which may include entrained gases, free solids, and totally dissolved solids) by physical or mechanical action, includes a bare pump, and, if included by the manufacturer at the time of sale, mechanical equipment, driver, and controls. 10 CFR 431.462. DPPPs, which are the subject of this notice of proposed rulemaking (''NOPR''), meet this definition of a pump and are covered under the pump equipment type.

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316; 42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a) and 42 U.S.C. 6316(b); 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6297)

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use, and estimated annual operating cost of a given type of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)–(3))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered equipment, including DPPPs, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6314(a)(1)(A))

In addition, if the Secretary determines that a test procedure amendment is warranted, the Secretary must publish the proposed test procedures in the **Federal Register** and afford interested persons an opportunity (of not less than 45 days' duration) to present oral and written data, views, and arguments on the proposed test procedures. (42 U.S.C. 6314(b)). If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. (42 U.S.C. 6314(a)(1)(A)(ii))

DOE is publishing this NOPR in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6314(a)(1)(A))

B. Background

DOE's existing test procedures for DPPPs appear at 10 CFR 431.464(b) and at 10 CFR 431 subpart Y, appendix B (''appendix B'') [3] and appendix C (''appendix C''). Any representations made on or after July 19, 2021, with respect to the energy use or efficiency of dedicated-purpose pool pumps subject to testing pursuant to 10 CFR 431.464(b), must be made in accordance

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

[3] On February 5, 2018 but before July 19, 2021, any representations made with respect to the energy use or efficiency of dedicated-purpose pool pumps subject to testing pursuant to 10 CFR 431.464(b) must be made in accordance with the results of testing pursuant to appendix B. *See* Note to appendix B to subpart Y of part 431.

with the results of testing pursuant to appendix C. Reflecting the circumstances when the existing test procedure was promulgated, any representations made after February 5, 2018 but before July 19, 2021 with respect to the energy use or efficiency of dedicated-purpose pool pumps must have been made in accordance with the results of testing pursuant to appendix B.

DOE established the currently applicable test procedures for DPPPs in a final rule published on August 7, 2017. 82 FR 36858 (''August 2017 TP Final Rule''). DOE established the currently applicable energy conservation standards for DPPPs in a direct final rule published on January 18, 2017. 82 FR 5650 (''January 2017 ECS Direct Final Rule''). The test procedure and standards established by these final rules were based on the recommendations of the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') DPPP 2017 Working Group (''DPPP Working Group''). The test procedure and standards for DPPPs are based on the weighted energy factor (''WEF'') metric.

On January 24, 2022, DOE published a request for information (''RFI'') undertaking a review to determine whether amendments are warranted for the test procedures for DPPPs. 87 FR 3457 (''January 2022 TP RFI''). DOE received comments in response to the January 2022 TP RFI from the interested parties listed in Table I.1.

TABLE I.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE JANUARY 2022 TP RFI

Commenter(s)	Reference in this NOPR	Comment No. in the docket	Commenter type
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Natural Resources Defense Council, Northwest Energy Efficiency Alliance.	ASAP et. al	8	Efficiency Organizations.
Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison; collectively, the California Investor-Owned Utilities.	CA IOUs	10	Utilities.
California Energy Commission and New York State Energy Research and Development Authority.	CEC and NYSERDA	9	State Agencies.
Fluidra	Fluidra	7	Manufacturer.
NSF International	NSF	4	Industry Association.
Pool and Hot Tub Alliance	PHTA	6	Industry Association.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[4] DOE notes that the docketed comments from PHTA and Fluidra include responses to both the January 2022 TP RFI as well as to an RFI related to DPPP energy conservation standards. 87 FR 3461 (''January 2022 ECS RFI''). In this NOPR, DOE addresses only the comments related to the January 2022 TP RFI as well as certain comments related to the January 2022 ECS RFI that have to do with definitions and test procedure. The remainder of comments related to the January 2022 ECS RFI will be addressed in a separate standards rulemaking.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes to update 10 CFR 431.462, 10 CFR 431.463, 10 CFR 431.464, and appendices B and C to subpart Y of 10 CFR part 431 as follows: (1) codify the scope of the DPPP test procedure consistent with DOE's current enforcement policy pertaining to DPPPs that cannot be appropriately tested by the current DOE test procedure; (2) update references to industry test standards to reflect current industry practices; (3) align DOE's DPPP definitions with DOE's corresponding DPPP motor definitions; and (4) remove the current test procedure at appendix B, which is obsolete. DOE's proposed actions are summarized in Table II.1 compared to the current test procedure as well as the reason for the proposed change. DOE notes that it is reprinting the entirety of the proposed appendix B, which is the current appendix C renamed to appendix B with amendments as proposed, with formatting changes. All substantive proposals are summarized in Table II.1.

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Proposed test procedure	Attribution
DOE issued an enforcement policy pertaining to certain types of DPPPs that were not considered during the development of the test procedures and currently applicable energy conservation standards for DPPPs.	Codify the enforcement policy in 10 CFR 431.464 by explicitly excluding these certain pumps from the scope of DOE's DPPP test procedure.	Improve clarity of test procedure.
References NSF/American National Standards Institute (''ANSI'')/Canadian Standards Association (''CAN'') 50–2015, Hydraulic Institute (''HI'') 40.6–2016.	Adopts latest versions of these referenced industry standards.	Harmonize with updated industry standard.
Not all definitions relevant to DPPP in 10 CFR 431.462 are aligned with definitions specified for DPPP motors in 10 CFR 431.483.	Amends the following pump definitions in 10 CFR 431.462 to align with the corresponding DPPP motor definitions in 10 CFR 431.483: multi-speed dedicated-purpose pool pump, variable-speed dedicated-purpose pool pump, dedicated-purpose pool pump motor total horsepower, rigid-electric spa pump motor. Adds definitions for drive and maximum operating speed.	Improve clarity of test procedure.

[4] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for DPPPs. (Docket No. EERE–2022–BT–TP–0003, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

TABLE II.1—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE—Continued

Current DOE test procedure	Proposed test procedure	Attribution
Appendix B was required for any representations made with respect to the energy use or efficiency of DPPPs between February 5, 2018 and July 19, 2021.	Removes appendix B, which is now obsolete, and renames appendix C as appendix B.	Improve clarity of test procedure.

DOE has tentatively determined that the proposed amendments described in section III of this NOPR would not alter the measured efficiency of DPPPs or require retesting or recertification solely as a result of DOE's adoption of the proposed amendments to the test procedures, if made final. Additionally, DOE has tentatively determined that the proposed amendments, if made final, would not increase the cost of testing. Discussion of DOE's proposed actions are addressed in detail in section III of this NOPR.

III. Discussion

In the following sections, DOE proposes certain amendments to its test procedures for DPPPs. For each proposed amendment, DOE provides relevant background information, explains why the amendment merits consideration, discusses relevant public comments, and proposes a potential approach.

A. Scope of Applicability

DOE's test procedures for DPPPs apply to the following types of DPPPs that are served by single-phase or polyphase input power: (1) self-priming pool filter pumps, (2) non-self-priming pool filter pumps, (3) waterfall pumps, and (4) pressure cleaner booster pumps. 10 CFR 431.464(b)(1)(i)–(ii). These test procedures do not apply to (1) submersible pumps or (2) self-priming and non-self-priming pool filter pumps with hydraulic output power greater than or equal to 2.5 horsepower. 10 CFR 431.464(b)(1)(iii).

The scope of the DPPP test procedure as defined at 10 CFR 431.464(b)(1) is consistent with the scope recommended by the DPPP Working Group. As part of its consideration of test procedure and standards for DPPPs, the DPPP Working Group determined that very large pool filter pumps are most commonly installed in commercial applications, where the head and flow characteristics are significantly different from residential installations. Because of these differences, the DPPP Working Group concluded that a test procedure for very large pool filter pumps would have required different load points than those established for residential pool pumps. Additionally, it was determined that for very large pool filter pumps, changes in the equipment such as pipe diameter made system curve C unrepresentative of such equipment (see below for further information on system curves). (Docket No. EERE–2015–BT–STD–0008, No. 53 at p. 190–191, 197–199). The DPPP Working Group also discussed very large pool filter pumps' use of motors which are already subject to DOE standards and which are generally higher efficiency than motors of smaller pool filter pumps. (Docket No. EERE–2015–BT–STD–0008, No. 79, p. 40).

During the course of the DPPP Working Group negotiations, a hydraulic output of 2.5 hydraulic horsepower (''hhp'') was discussed as the threshold value that differentiates residential pool filter pumps from the type of very large pool filter pumps most commonly installed in commercial applications. (Docket No. EERE–2015–BT–STD–0008, No. 79 at p. 33–34, p. 39, p. 41–42, p. 44–48, p. 50–53). The identification of 2.5 hhp as the threshold was based on identifying the DPPP with largest hhp in the California Energy Commission's certification database,[5] which was presumed to include pumps used only in residential applications. The DPPP Working Group also noted a lack of performance data for very large pool filter pumps, which prevented the group from negotiating standards for these pumps. Consequently, the DPPP Working Group did not recommend a test procedure for these pumps. (Docket No. EERE–2015–BT–STD–0008, No. 79 at p. 33–34, p. 39, p. 41–42, p. 44–48, p. 50–53). Consistent with the recommendations of the DPPP Working Group, DOE did not adopt a test procedure or standards for pool filter pumps with hydraulic output power greater than or equal to 2.5 hhp in the August 2017 TP Final Rule. 82 FR 36858, 36872.

Subsequent to the adoption of the test procedure and energy conservation standards for DPPPs, DOE became aware of several models of DPPPs that are designed and marketed for commercial applications but that do in fact have hydraulic output power less than 2.5 hhp. These pumps are also characterized as having an orifice with inner diameter of greater than 2.85 inches and a measured performance of greater than or equal to 200 gallons per minute (''gpm'') at 50 feet of head, as measured in accordance with the DOE test procedure. The Office of the General Counsel issued an enforcement policy statement regarding these DPPPs (''DPPP Enforcement Policy'').[6] The DPP Enforcement Policy explained that these pumps were considered to be different from dedicated-purpose pool pumps considered during the DPPP Working Group negotiations, but were not explicitly exempted in the regulatory text of the August 2017 TP Final Rule and January 2017 ECS Direct Final Rule. The policy states that DOE will not enforce the testing, labeling, certification, and standards compliance requirements for DPPPs meeting all of the following three criteria: (1) the orifice on the pump body that accepts suction side plumbing connections has an inner diameter of greater than 2.85 inches; (2) the pump has a measured performance of ≥200 gpm at 50 feet of head as determined in accordance with appendix B or appendix C (as applicable) to subpart Y of part 431, section I.A.1 (when determining overall efficiency, best efficiency point, or other applicable pump energy performance information, section 40.6.5.5.1, ''Test procedure''; section 40.6.6.2, ''Pump efficiency''; and section 40.6.6.3, ''Performance curve'' must be used, as applicable); and (3) the pump is marketed exclusively for commercial applications.

In the January 2022 TP RFI, DOE requested comment on whether it should expand the scope of the DPPP test procedure to include pumps designed for commercial applications, including those subject to the DPPP Enforcement Policy and/or pool filter pumps with hydraulic output power greater than or equal to 2.5hhp. 87 FR 3457, 3460. DOE also sought information on which test points and

[5] California Energy Commission's Modernized Appliance Efficiency Database System, available at: *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx*.

[6] *www.energy.gov/gc/articles/direct-purpose-pool-pumps-enforcement-policy*.

system curves [7] would be appropriate to measure performance of these DPPPs. *Id.* The following sections discuss comments received and DOE's consideration of pool filter pumps with hydraulic output power greater than or equal to 2.5 hhp and pumps subject to the DPPP Enforcement Policy.

1. Pool Filter Pumps With Hydraulic Output Power ≥2.5 HHP

The PHTA stated that DOE should not expand the scope of the DPPP test procedure to include commercial pumps with 2.5 hhp or greater, as these pumps cover a wide range of applications and are subject to strict public health regulations. (PHTA, No. 6, pp. 13–14) The PHTA further commented that if these large pumps are pursued, the scope would need to be narrowed (*e.g.,* capped at 5 hhp or single-phase motors only). (*Id.*) Fluidra stated that the scope and range of commercial pumps above 2.5 hhp is varied and vast, and that DOE should consider limiting the scope of coverage for commercial DPPPs to single speed DPPPs that fall under DOE's DPPP Enforcement Policy. Fluidra stated that before extending the scope further, DOE would need to conduct a new analysis and develop a new test method with industry as for commercial applications, pipe sizes range from 3-to-12-inch plumbing, and only system Curves A, B, and C [8] have been commonly accepted by industry. (Fluidra, No. 7, pp. 9–10)

The PHTA also stated that DOE would need to determine a new test point to develop an appropriate system curve because the current test procedure is based on the system curve C, on which the larger DPPPs do not operate. (PHTA, No. 6, p. 14) This new test procedure would need to also determine the plumbing size, hhp categories, and appropriate curve per those categories. *Id.*

DOE noted in the August 2017 TP Final Rule that the system curve C on which DOE's current DPPP test procedure is based [9] was initially developed to be representative of 2.5-inch plumbing. 82 FR 36858, 36879. Additionally, section 4.1.2.1.3 of ANSI/Association of Pool and Spa Professionals (''APSP'')/International Code Council (''ICC'')–15a–2013 [10] describes curves A, B, and C as ''approximately'' representative of 2.0-inch, 1.5-inch, and 2.5-inch diameter pipe, respectively, as noted in the 2016 NOPR that preceded the August 2017 TP Final Rule. 81 FR 64580, 64598 (September 20, 2016) (''2016 TP NOPR'').

ASAP et. al, CEC and NYSERDA, and the CA IOUs commented that DOE should develop a test procedure to cover large commercial pool pumps. These commenters each cited a study by Worth *et al.* (''Worth *et al.* study'') [11] that estimated that while large public pools comprise only 2 percent of the total in-ground pools, they account for 49 percent of total pool pump energy use. (ASAP et al., No. 8, p. 1; CEC and NYSERDA, No. 9, p. 2; CA IOUs, No. 10, p. 2) The CA IOUs noted that the current scope of the DPPP products test procedure was limited to products below 2.5 hhp, and that the corresponding standards had yielded significant energy savings. (CA IOUs, No. 10, p. 2) The CA IOUs stated that the Worth *et al.* study demonstrates that the large commercial pool pump market consumes approximately the same electrical energy as pool pumps subject to DOE's DPPPs regulations. The CA IOUs also commented that the study cited an aquatic management system field study that reported at least 25 percent savings due to the use of variable speed controls compared to conventional baseline pumps at each large commercial pump installation, indicating significant energy savings potential. (CA IOUs, No. 10, pp. 2–3) Therefore, the CA IOUs recommended that DOE develop a test procedure for pumps above 2.5 hhp. *Id.*

The PHTA stated that DOE should not include commercial DPPPs, noting that there are 258,366 commercial pools, which represents 4.67% of the United States pool market, and that many pool pumps used in smaller commercial pools such as hotels or condos are already captured by the DPPP rule. The PHTA stated it lacked data on how many pumps larger than 2.5 hhp are currently utilized, but noted that many of these larger commercial pools likely use single speed pumps and that of those three-phase pumps in use most used VFDs. PHTA further added that most commercial pool applications are engineered to ensure proper turnover rates that ensure compliance with state public health and safety regulations and national industry codes and standards. PHTA stated that it believes the challenges of expanding the scope or developing a separate test procedure far outweigh the benefits. (PHTA, No. 6, p. 14).

ASAP et. al stated that because of the differences in head and flow characteristics between commercial and residential pool applications, DOE should investigate the representative test points and system curves for DPPPs designed for commercial pool applications. Such a test procedure would give consumers access to energy efficiency information based on a standardized test method. (ASAP et al., No. 8, p. 1)

With regard to the development of a system curve for large commercial pool pumps, the CA IOUs noted that the DPPP Working Group had discussed potential low- and high-flow operating points for DPPPs with larger than 2.5 hhp. (CA IOUs, No. 10, p. 3) The CA IOUs encouraged DOE to continue this development, and expressed support for using a constant head system curve rather than Curve C as the DPPP Working Group had recommended. To support its recommendation, the CA IOUs presented field data collected by HMW International Inc. from 47 large commercial pools in California of varying sizes and filtration flow rates.[12] The CA IOUs stated that the study showed a somewhat consistent linear trend between flow rate and power, indicating that flow rate is the primary source energy demand variation. The CA IOUs explained that this trend is attributable to the rule of thumb used by industry in which these systems are designed using an end-suction closed coupled pump with an assumed constant head pressure of 60 to 70 feet. The CA IOUs asserted that although this constant head pressure assumption is different from the 47 feet of head in the 200 to 500 gpm (2 to 7 hhp) range

[7] A system curve is a graphical representation of the relationship between flow rate and the associated head losses.

[8] A set of standardized system curves has been developed for DPPPs, designated as A, B, C, and D. Curves A, B, and C were developed by Pacific Gas and Electric based data from an exercise by ADM Associates, Inc. in 2002, *Evaluation of Year 2001 Summer Initiatives Pool Pump Program* and input from industry experts. The Australia state and territory governments and the New Zealand government operate the Energy Rating Labeling Program rely on Australian Standard (AS) 5102–2009, ''Performance of household electrical appliances—Swimming pool pump—units, Parts 1 and 2'' (AS 5102–2009) which utilizes system curve D.

[9] Specifically, for self-priming pool filter pumps and non-self-priming pool filter pumps, Table 1 of appendix C specifies a head equation corresponding to system curve B (*i.e.,* $H = 0.0082 \times Q^2$).

[10] ANSI/APSP/ICC–15a–2013, ''American National Standard For Residential Swimming Pool And Spa Energy Efficiency.''

[11] Worth, C., T. Rosenfeld, G. Gockel, and G. Fernstrom. ''A Cannonball of Opportunity: The Hidden Savings Potential from Large Public Swimming Pools.'' Proceedings from the 2018 ACEEE Summer Study on Energy Efficiency in Buildings.

[12] *Ibid,* 3–8.

assumed by the DPPP Working Group,[13] the use of a constant head test method approach for this equipment appears to be practical and supported by field data. The CA IOUs stated that DOE should work with industry to refine the system curve and design head assumptions based on current practices and field data in order to propose a test method for the larger commercial DPPPs. (CA IOUs, No. 10, pp. 3–4)

In this NOPR, DOE is not proposing a test procedure for DPPPs with greater than 2.5 hhp. Regarding comments to develop the appropriate system curve and test load points for DPPPs with greater than 2.5 hhp, DOE notes that the DPPP Working Group discussed potential test procedures for DPPPs with greater than 2.5 hhp, but did not come to consensus on such a test procedure. The DPPP Working Group discussed how, unlike DPPPs with less than 2.5 hhp which are typically installed in residential applications, very large pool filter pumps are more commonly installed in commercial applications with significantly different and variable head and flow characteristics than those applicable to residential applications. (Docket No. EERE–2015–BT–STD–0008, CA IOUs No. 53 at p. 197–200) Therefore, the DPPP Working Group determined that any test procedure for very large pool filter pumps (*i.e.,* those over 2.5 hhp) would require unique load points and system curves. (Docket No. EERE–2015–BT–STD–0008, No. 53 at p. 190–191). The DPPP Working Group considered system curves other than curve C and ultimately considered a constant head test method for larger DPPPs, as noted by the CA IOUs, with discussion regarding a potential discontinuity at 2.5 hhp.[14] The CA IOUs comment cites a study that would support a different constant head value than that discussed by the DPPP Working Group for pumps over 2.5 hhp. In addition, as discussed in section III.A.2, commenters recommended considering system curves D and E for pumps near 2.5 hhp and subject to the enforcement policy. (CA IOUs, No. 10, p. 2; CEC and NYSERDA, No. 9, p. 2) DOE notes that the use of differing system curves, including constant head curves, across different categories or sizes of DPPPs, would cause discontinuities in ratings at the hhp boundaries, which could cause confusion in the marketplace due to the inability to correctly compare products in that space. DOE also lacks access to and data regarding the distribution of pool commercial pool sizes, which would be necessary to independently verify and to develop a test procedure.

Therefore, at this time, DOE does not have sufficient field data or performance characteristics to properly develop a test procedure appropriate for DPPPs with greater than 2.5 hhp. DOE has not been made aware of or received any additional data subsequent to the DPPP Working Group process that would allow it to develop a test procedure that is representative for DPPPs with greater than 2.5 hhp. If DOE determines in a final rule not to expand the scope, DOE will continue to monitor the commercial pool market and regulatory environment and reassess the scope of its test procedure in the future.

In addition, DOE reviewed the Worth *et al.* study cited by ASAP et al., CEC and NYSERDA, and the CA IOUs. The report recommends developing standards to support incentives for variable speed technology retrofits on pumps used in large public pools. DOE notes, however, that the report identifies several barriers to using variable speed technology pumps in public pools, including restrictive health codes as well as a lack of best practices, control technology, and training specific to the public pool industry.[15] These barriers to installing more efficient pumps in public pools suggests that lack of a DOE test procedure and accompanying energy conservation standard for DPPPs with greater than 2.5 hhp is not a key barrier hindering the achievement of pool pump efficiency in large commercial pools. DOE is also concerned that should DOE receive data allowing DOE to develop a representative test procedure for these DPPPs, developing such test procedures and standards may create conflict with health and safety codes that are applicable to most use cases for these DPPPs. DOE welcomes comment on this issue.

For the reasons discussed in this section, in this NOPR, DOE is not proposing a test procedure specific to DPPPs with hydraulic output power greater than 2.5 hhp.

DOE requests comment on its preliminary determination not to propose a test procedure specific to DPPPs with hydraulic output power greater than 2.5 hhp. DOE also requests data that would allow it to develop such a test procedure if it was determined to be warranted, including distribution of commercial pool sizes and piping, distribution of head and flow requirements across applications in consideration of current health and safety codes, and distribution of single speed and variable speed installations.

2. Pumps Subject to DOE's DPPP Enforcement Policy

The CA IOUs commented that DOE should develop a test method for the DPPPs near 2.5 hhp that meet the criteria of the DPPP Enforcement Policy, and that this criteria could be used to identify a unique equipment class of self-priming pool pumps that requires separate testing conditions from conventional self-priming pool pumps. The CA IOUs noted that the system curve C is reportedly not appropriate for testing due to larger suction and outlet side plumbing that would lower the total dynamic head for a given flow. The CA IOUs stated the current test procedure is based on system curve C, which represents approximately 2.5-inch plumbing with total dynamic head representative of residential pools. The CA IOUs stated DOE should work with industry to determine if curve D[16] or a new curve E would be a more appropriate option for these larger DPPPs (*i.e.,* that are near 2.5 hhp but covered by the DPPP Enforcement Policy) and validate the effectiveness of the curve including the minimum gpm value. They further stated that DOE should collect data on both residential and commercial products and work with industry to estimate a suitable minimum flow requirement for the low-speed operating point for this potential equipment class. (CA IOUs, No. 10, p. 2)

CEC and NYSERDA recommended that DOE amend the test procedure to ensure that pumps subject to the DPPP Enforcement Policy can be appropriately tested, and that doing so would eliminate the need for the enforcement policy. (CEC and NYSERDA, No. 9, p. 1) They noted that the DPPP Enforcement Policy was only needed because the failure to consider

[13] See transcript from negotiations resulting in the January 2017 ECS Direct Final Rule: Docket No. EERE–2015–BT–STD–0008, No. 95, pp. 188–197.

[14] See transcript from negotiations resulting in the January 2017 ECS Direct Final Rule: Docket No. EERE–2015–BT–STD–0008, No. 95, p. 188–197; Docket No. EERE–2015–BT–STD–0008, No. 63, p. 2. See for example, presentation from negotiations: Docket No. EERE–2015–BT–STD–0008, No. 60, p. 143–147.

[15] Worth, C., T. Rosenfeld, G. Gockel, and G. Fernstrom. ''A Cannonball of Opportunity: The Hidden Savings Potential from Large Public Swimming Pools.'' Proceedings from the 2018 ACEEE Summer Study on Energy Efficiency in Buildings, pp. 2–3.

[16] An Australian standard for pool pump units, AS 5102.1:2019, ''Performance of household electrical appliances—Swimming pool pump-units Measurement of energy consumption and performance,'' uses system curve D. Additionally Pentair has referenced curve D in comments to ENERGY STAR as reflective of the hydraulic conditions of larger pools. (Available at *www.energystar.gov/sites/default/files/specs/Pentair%20Comments.pdf*).

such DPPPs by the DPPP Working Group was an oversight, and that DOE should take the opportunity to correct this oversight by amending the test procedure to appropriately test those DPPPs. *Id.* CEC and NYSERDA further stated that, as discussed in the DPPP Working Group, curve D and E [17] can be a starting point for a potential system curve for testing these DPPPs, which are not intended to run on Curve C. (CEC and NYSERDA, No. 9, p. 1)

PHTA and Fluidra commented that DOE should codify DOE's DPPP Enforcement Policy. (PHTA, No. 6, p. 14, Fluidra, No. 7, p. 2)

As discussed in section III.A of this document, the pumps subject to the DPPP Enforcement Policy are designed for commercial pool applications and exhibit head and flow characteristics that are significantly different from residential installations. These commercial applications also include a much wider range of piping system sizes and features and this range would not allow DOE to create a system curve from DOE's existing data that would be representative of these pumps. As such, the current DOE test procedure would not produce test results that are representative for pumps with hydraulic output power less than 2.5 hhp that are designed and marketed for use in commercial pool applications.

In this NOPR, DOE is not establishing test procedures specific to the pumps subject to the DPPP Enforcement Policy for the same reasons described in section III.A.1 of this NOPR regarding DOE's determination not to establish test procedures for DPPPs with hydraulic output power greater than 2.5 hhp—namely: (1) because any test procedure for pumps with hydraulic output power less than 2.5 hhp that are designed and marketed for use in commercial pool applications would require unique load points and system curves, and DOE does not have sufficient data or any further information than it did at the time of the August 2017 TP Final Rule to develop a test procedure appropriate for such pumps and to consider the implications of discontinuities at the capacity boundaries, and (2) that DOE has tentatively determined that any benefits of such a test procedure would be outweighed by potential complications with health and sanitation codes.

In addition, since the test procedure would not produce results that are representative for pumps covered by DOE's DPPP Enforcement Policy, DOE is proposing to amend the test procedure scope language at 10 CFR 431.464(b)(1)(iii) to make explicit that DPPPs meeting the three criteria specified in DOE's DPPP Enforcement Policy are excluded from the scope of the test procedure, with one modification to the second criterion. The second criterion specifies that the pump have a measured performance of ≥200 gpm at 50 feet of head as determined in accordance with appendix B or C (as applicable) to subpart Y of 10 CFR part 431, section I.A.1 (When determining overall efficiency, best efficiency point, or other applicable pump energy performance information, section 40.6.5.5.1, ''Test procedure''; section 40.6.6.2, ''Pump efficiency''; and section 40.6.6.3, ''Performance curve'' must be used, as applicable.). Because DOE has tentatively determined that the DPPP test procedure is not applicable to these DPPPs, DOE is proposing to remove the reference to the DPPP test procedure appendix and instead specify that the measured gpm performance at 50 feet of head be determined in accordance with section 40.6.5.5.1, ''Test procedure'' and section 40.6.6.3, ''Performance curve'' of HI 40.6–2021.'' This is not a substantive change because the revision would more explicitly reference the applicable sections of the industry standard rather than referencing the DPPP test procedure that includes those references.

Further, DOE is proposing to establish additional product-specific enforcement provisions for DPPPs at 10 CFR 429.134(i)(2) that would specify how DOE would determine whether a given pump satisfies the criteria of having a measured performance of ≥200 gpm at 50 feet of head. Specifically, DOE is proposing to specify that DOE would use section 40.6.5.5.1, ''Test procedure'' and section 40.6.6.3, ''Performance curve'' of HI 40.6–2021, to determine the flow rate or gpm of the DPPP model at 50 feet of head, and will use the mean of the measurement (either the measured flow rate for a single unit sample or the average of the measured flow rates for a multiple unit sample) to determine the applicable standard, if any. As discussed, these DPPPs are distinguished by having an orifice with inner diameter of greater than 2.85 inches; a measured performance of ≥200 gpm at 50 feet of head as determined in accordance with appendix C, and are marketed exclusively for commercial applications.

DOE requests comment on its preliminary determination not to propose a test procedure specific to DPPPs currently subject to the DPPP Enforcement Policy. DOE also requests data related to the applications these DPPPs serve including pool size, piping size, and minimum head and flow requirements. DOE also requests any data and information related to development of a curve E, as well data indicating how such a curve was determined (or could be determined) to be representative of this set of pumps. DOE further requests comment on its proposal to amend the Scope section of the test procedure to explicitly exclude such pumps from the scope of the test procedure.

3. Certain Self-Priming Pumps and Waterfall Pumps

DOE also received comments in response to the January 2022 TP RFI regarding the application of DOE's DPPP Enforcement Policy with respect to certain self-priming pumps and waterfall pumps.

Referencing a Pentair presentation submitted to the CEC, the CA IOUs stated that some self-priming DPPPs used in residential applications meet the enforcement policy criteria when a vanishing edge water feature is present. The CA IOUs commented that DOE should revisit the criteria specifying ''marketed exclusively for commercial applications'' to ensure that residential DPPPs are not also adversely impacted by the DOE test procedure rating conditions. (CA IOUs, No. 10, p. 2) DOE acknowledges that one of the pumps shown in that presentation could be subject to DOE's DPPP Enforcement Policy based on performance curve alone. However, DOE believes it would be excluded from the enforcement policy based on orifice size and marketing, indicating that curve C may be more representative for this pump than for pumps subject to the enforcement policy, and that this particular pump was likely among those intended to be subject to standards. As such, DOE is not proposing any changes to the provisions of the enforcement policy as they are proposed to be applied to the scope of the test procedure, discussed in section III.A.2.

The PHTA commented that DOE should consider defining ''commercial waterfall pumps'' because not all such pumps meet the DPPP Enforcement Policy criteria that specifies performance of ≥200 gpm at 50 feet of head. The PHTA commented that DOE should create two separate categories for ''waterfall pump'' to address different sizes and ensure that those intended for commercial applications are addressed differently. (PHTA, No. 6, p. 3, 14) Fluidra also commented that the

[17] Although a ''curve E'' was mentioned during discussions in the DPPP Working Group, DOE is not aware of a curve E having been developed or used by the pool pump industry.

commercial application of waterfall pumps should be included in the scope of DOE's DPPP Enforcement Policy. Fluidra commented that DOE should define ''commercial waterfall pumps'' to meet the definition of ''waterfall pump'' at 10 CFR 431.462 and also meet criteria 1 and 3 of the DOE's DPPP Enforcement Policy: (1) the orifice on the pump body that accepts suction side plumbing connections has an inner diameter of greater than 2.85 inches and (3) the pump is marketed exclusively for commercial applications. (Fluidra, No. 7, p. 2)

DOE notes that the definition of waterfall pump at 10 CFR 431.462 is limited to pool filter pumps with a certified maximum head less than or equal to 30.0 feet, and a maximum speed less than or equal to 1,800 rpm. Any pump with a certified maximum head less than or equal to 30.0 feet would not be capable of meeting the second criteria of the DPPP Enforcement Policy, which specifies a certain flow rate level at 50 feet of head. Therefore, a DPPP meeting the waterfall pump definition would never be included in the scope of the DOE DPPP Enforcement Policy, including as DOE proposes to codify the DPPP Enforcement Policy in this NOPR. Fluidra's proposal indicates that orifice diameter (criteria 1) and marketing (criteria 3) should be sufficient to distinguish commercial waterfall pumps from other waterfall pumps and that commercial waterfall pumps should be included in the DPPP Enforcement Policy. (Fluidra, No. 7, p. 2) DOE has tentatively determined that these conditions are not sufficient to warrant different treatment. In particular, both marketing and orifice size can be changed—for example, an adapter could be used to apply a pump with a larger orifice to a smaller pipe diameter. Furthermore, although curve C was selected as the most representative system curve for the DOE test procedure, not all DPPPs subject to the test procedure will be applied to 2.5 inch pumping. It was the combination of significantly different hydraulic conditions (in the form of the pump curve) as well as presumably different piping sizes and marketing, that was used to identify DPPPs that were hydraulically different from those considered by the DPPP Working Group and to establish the enforcement policy criteria.

For the reasons discussed, DOE has no technical basis with which to propose excluding certain waterfall pumps from the test procedure scope based solely on orifice size and marketing. Therefore, DOE has tentatively determined not to propose a separate definition for commercial waterfall pumps and to maintain the single definition at 10 CFR 431.462.

DOE further notes that no certification requirements or energy conservation standards currently apply to DPPPs meeting the current definition of waterfall pump at 10 CFR 431.462. 10 CFR 429.59; 10 CFR 431.465. When DOE selected Trial Standard Level 3 as the energy conservation standard for DPPPs, this standard did not establish a standard level for waterfall pumps. 82 FR 5650, 5663, 5715, 5735. As such, waterfall pumps as defined are subject only to the test procedure should a manufacturer choose to make representations.

B. Updates to Industry Standards

The test conditions, methods, and measurements described in appendix C reference certain sections of several industry standards, as described further throughout this section. Several of the referenced industry test standards have been updated by industry since DOE established its test procedures. The currently referenced 2014 version [18] of HI 40.6 (''HI 40.6–2014'') has been updated to a 2021 version [19] (''HI 40.6–2021''); the currently referenced 2015 version [20] of NSF/ANSI 50 (''NSF/ANSI 50–2015'') has been updated to a 2019 version [21] (''NSF/ANSI/CAN 50–2019''), followed by a 2020 version [22] (''NSF/ANSI/CAN 50–2020''); and the currently referenced 2014 version [23] of CSA C747–2009 (''CSA C747–2014'') has been updated to a 2019 version [24] (''CSA C747–2019''). In the January 2022 TP RFI, DOE requested comment on the updated standards HI 40.6–2021 and NSF/ANSI/CAN 50–2019 [25] and whether they should be incorporated by reference for the DPPP test procedure. 82 FR 3457, 3460–3461.

The PHTA stated that its members are in overall support of using the latest editions of most standards but need more time to review the latest edition of HI 40.6 to assess its impact. Regarding updating to the 2020 version of NSF/ANSI/CAN 50, PHTA stated that DOE should use this version, and Fluidra stated that use of this version is acceptable if there are no changes to the test method. (Fluidra, No. 7, p. 10; PHTA, No. 6, p. 14–15)

The PHTA and Fluidra stated that if updates to the latest editions of industry standards require re-testing, those updates would pose a significant burden to manufacturers. (PHTA, No. 6, p. 14–15; Fluidra, No. 7, p. 10) The PHTA stated that members would not want to invest in such a re-testing effort for existing pumps on the market, and that they presumed that any revised DPPP rule would require only new pumps to be tested to the latest editions of industry standards. (PHTA, No. 6, p. 14–15)

NSF commented that it supports retaining and updating NSF/ANSI/CAN 50 for DOE's DPPP test procedure. NSF stated that the section of NSF/ANSI/CAN 50 that is referenced in DOE's DPPP test procedure has only changed from being labeled C3 to N–3.3 and that the performance requirements in the section remain the same. (NSF, No. 4, pp. 1–2)

Appendix C states that the WEF of DPPPs must be determined in accordance with HI 40.6–2014 (with the exception of certain sections of the industry standard). Appendix C references HI 40.6–2014 with regards to equipment, test conditions and tolerances, and data collection and stabilization. DOE's review of the 2021 version of HI 40.6 indicates that updates are mainly limited to nomenclature and definitions,[26] non-substantive changes to section titles, and the inclusion of a new appendix for the testing of circulator pumps. DOE does not need to reference the new appendix for the DOE DPPP test procedure. Regarding the HI 40.6 sections referenced in appendix C of the DOE test procedure, the title of section 40.6.4, ''Considerations when determining the efficiency of a pump'' has been changed to ''Considerations when determining the efficiency of certain pumps.'' Section A.7 of HI 40.6, ''Testing at temperatures exceeding 30

[18] Hydraulic Institute, *Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing,* Approved 2014.

[19] Hydraulic Institute, *Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing,* Approved February 17, 2021.

[20] NSF International, American National Standards Institute, *Equipment for Swimming Pools, Spas, Hot Tubs and Other Recreational Water Facilities,* Approved January 26, 2015.

[21] NSF International, American National Standards Institute, Canadian Standards Association, *Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities,* Approved 2019.

[22] NSF International, American National Standards Institute, Canadian Standards Association, *Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities,* Approved October 21, 2020.

[23] Canadian Standards Association, *Energy efficiency test methods for small* motors, Approved August 2016.

[24] Canadian Standards Association, *Energy efficiency test methods for small motors,* Approved 2019.

[25] As discussed later in this section, the 2020 version of NSF/ANSI/CAN 50 was released subsequent to the analysis conducted in support of the January 2022 TP RFI.

[26] ANSI/HI 14.1–14.2 ''Rotodynamic Pumps for Nomenclature and Definitions''.

°C (86 °F)'', which the DOE test procedure currently directs not be used, has been removed. Further, in the test procedure NOPR for commercial and industrial pumps published on April 11, 2022, DOE tentatively determined that with respect to the provisions of HI 40.6–2014, the corresponding provisions of HI 40.6–2021 are substantively the same and that adopting such provisions would not change the current test procedure. 87 FR 21268, 21285. Based on these considerations, DOE has tentatively determined the updates in HI 40.6–2021 are non-substantive and will neither affect testing nor result in different test outcomes for the measured values of DPPPs. DOE proposes to incorporate by reference HI 40.6–2021 and update the DPPP test procedure by replacing references to HI 40.6–2014 with HI 40.6–2021. Since HI 40.6–2014 would no longer be referenced if DOE were to finalize the test procedure as proposed, DOE also proposes to remove the incorporation by reference of HI 40.6–2014 by way of replacing it with HI 40.6–2021 at 10 CFR 431.463(d)(4).

Product-specific enforcement provisions at 10 CFR 429.134(i)(2)(iv)(A) also reference appendix A and section 40.6.3.2.2 of HI 40.6–2014. For similar reasons as stated in the above paragraph, DOE proposes to replace these references to HI 40.6–2014 with references to HI 40.6–2021.

Section F of appendix C references section C.3 of appendix C of NSF/ANSI 50–2015 with regards to determining the self-priming capability of a pump, which is necessary to determine if a DPPP meets DOE's definition of a self-priming or non-self-priming pump. In the January 2022 TP RFI, DOE noted that section N–3.3 of NSF/ANSI/CAN 50–2019 is the same as section C.3 of NSF/ANSI 50–2015. 87 FR 3457, 3460–3461. Subsequent to the time of analysis of the January 2022 TP RFI, a 2020 version of the standard was released. DOE reviewed the 2020 version and has determined that, like the 2019 version, section C.3 of NSF/ANSI 50–2015 is the same as section N3–3 of NSF/ANSI/CAN 50–2020. DOE's review of the content of these sections indicates no changes. DOE has tentatively determined that updates to the latest version will neither affect testing nor result in different test outcomes for the measured values of DPPPs. Therefore, DOE proposes to incorporate by reference NSF/ANSI/CAN 50–2020 and update the DPPP test procedure by replacing references to C.3 of NSF/ANSI 50–2015 with N–3.3 of NSF/ANSI/CAN 50–2020. DOE also proposes to remove the incorporation by reference of NSF/ANSI 50–2015 by way of replacing it with NSF/ANSI 50–2020 at 10 CFR 431.463(g)(1).

DOE did not request for comment on updating to CSA C747–2019 because it is simply a reaffirmed version of CSA C747–2014. Therefore, there are no changes to this test standards, and DOE proposes to incorporate by reference CSA C747–2019.

As discussed, the proposed updates to industry test standard references do not involve substantive changes to the test setup and methodology or impact measured values. DOE has tentatively determined that incorporation by reference of the latest versions will align DOE test procedures with the latest industry standards.

DOE requests comments on the proposal to incorporate by reference HI 40.6–2021, NSF/ANSI/CAN 50–2020, and CSA C747–2019 for appendix C.

C. Definitions

Definitions relevant to DOE's DPPP test procedure are specified at 10 CFR 431.462. In the January 2022 TP RFI, DOE requested comment on the definitions of DPPPs and DPPP varieties and whether any of the terms should be amended. In particular, DOE requested comment on whether the terms are sufficient to identify which equipment is subject to the test procedure and whether any test procedure amendments are required to ensure that all such equipment can be appropriately tested in accordance with the test procedure. 87 FR 3457, 3459.

The PHTA commented that no changes were needed to most of the existing definitions, with some exceptions. (PHTA, No. 6, p. 2)

The following sections discuss DOE's proposals to align certain DPPP definitions with definitions for DPPP motors, definitions pertaining to integral filters, and definitions pertaining to pool pump timers.

1. Aligning DPPP and DPPP Motor Definitions

On August 14, 2018, DOE received a petition submitted by a variety of entities (collectively, the ''Joint Petitioners'') [27] requesting that DOE issue a direct final rule to establish prescriptive standards and a labeling requirement for DPPP motors (''2018 DPPP Motor Petition'').[28] Appendix A of the 2018 DPPP Motor Petition included various recommended definitions pertaining to the proposal. In response to the January 2022 TP RFI, the PHTA stated that DOE should review the misalignment of definitions in the 2018 DPPP Motor Petition and DOE's test procedure final rule for DPPP motors that went into effect September 27, 2021. (PHTA, No. 6, p. 2–3, 12)

Specifically, the PHTA stated that the variable-speed and multi-speed definitions from the 2018 DPPP Motor Petition should be included in any update to current DPPP rules, and that DOE should refer to UL 1004–10 to capture those definitions. (PHTA, No. 6, p. 12) Fluidra commented that the 2018 DPPP Motor Petition, with all the included definitions for DPPP motors, should be adopted. (Fluidra, No. 7, p. 9)

On July 29, 2021, DOE published a final rule establishing a test procedure for DPPP motors. 86 FR 40765 (''September 2021 DPPP Motors Final Rule''). In that rule, DOE specified that the applicable definitions for DPPP motors are in Section 2 ''Glossary'' of UL 1004–10:2020 [29] and codified this specification in 10 CFR 431.483, ''Definitions.'' 86 FR 40765, 40769. In the September 2021 DPPP Motors Final Rule, DOE described that in the NOPR for that test procedure rulemaking, it had presented the main differences in definitions specified in UL 1004–10:2019 [30] and those recommended in the 2018 DPPP Motor Petition and, further, had asked for comment on its proposal to incorporate UL 1004–10:2019. 86 FR 40765, 40769. In response, the CA IOUs, National Electrical Manufacturers Association (''NEMA'') and PHTA during the comment period expressed agreement with incorporating UL 1004–10:2020. (Docket No. EERE–2017–BT–STD–0048, No. 64, p. 2; Docket No. EERE–2017–BT–STD–0048, No. 57, p. 3). DOE in the September 2021 DPPP Motors Final Rule then incorporated UL 1004–10:2020, having ascertained that this latest version made only minor editorial

[27] The petitioners included the following: The Association of Pool & Spa Professionals, Alliance to Save Energy, American Council for an Energy-Efficient Economy, Appliance Standards Awareness Project, Arizona Public Service, California Energy Commission, California Investor Owned Utilities, Consumer Federation of America, Florida Consumer Action Network, Hayward Industries, National Electrical Manufacturers Association, Natural Resources Defense Council, Nidec Motor Corporation, Northwest Power and Conservation Council, Pentair Water Pool and Spa, Regal Beloit Corporation, Speck Pumps, Texas ROSE (Ratepayers' Organization to Save Energy), Waterway Plastics, WEG Commercial Motors, and Zodiac Pool Systems.

[28] The 2018 DPPP Motor Petition is available at *www.regulations.gov/document/EERE-2017-BT-STD-0048-0014.*

[29] UL Standards. *Pool Pump Motors,* Published February 28, 2020.

[30] UL Standards. *Pool Pump Motors,* Published July 1, 2019.

updates and made no changes compared to the 2019 version. 86 FR 40765, 40770.

For this NOPR, DOE reviewed and compared the definitions in Section 2 ''Glossary'' of UL 1004–10:2020 for DPPP motors, as referenced in 10 CFR 431.483, with the definitions in 10 CFR 431.462 that pertain to DPPPs in order to identify any differences that may create conflict or confusion. UL 1004–10:2020 defines the following terms: (1) dedicated-purpose pool pump (DPPP) motor; (2) integral cartridge-filter pool pump motor, (3) integral sand-filter pool pump motor, (4) storable electric spa pump motor, (5) rigid-electric spa pump motor, (6) waterfall pump motor, (7) two-speed dedicated-purpose pool pump motor, (8) multi-speed dedicated-purpose pool pump motor, and (9) variable-speed control dedicated-purpose pool pump motor. DOE similarly defines each of these terms in 10 CFR 431.462, but as ''pumps'' without the word ''motor.''

The definition of dedicated-purpose pool pump motor in UL 1004–10:2020 specifies that it is an electric motor that is single-phase or poly-phase and is designed and/or marketed for use in dedicated-purpose pool pump applications. The definition of dedicated-purpose pool pump in 10 CFR 431.462 specifies different types of pumps that together comprise the broader definition of DPPP, but does not provide any specifications regarding motor components or intended applications.[31] Hence, the definition of dedicated-purpose pool pump in 10 CFR 431.462 does not conflict with the definition of dedicated-purpose pool pump motor definition in UL 1004–10:2020. Therefore, DOE has tentatively determined that the definition of dedicated-purpose pool pump in 10 CFR 431.462 does not need to be amended.

The definitions of integral cartridge-filter pool pump motor, integral sand-filter pool pump motor, and storable electric spa pump motor in UL 1004–10:2020 state that the motor is a component of the corresponding DPPP type as defined in 10 CFR 431.462. The definitions for these DPPP types in 10 CFR 431.462 do not provide any specifications regarding motor components. Hence, the definitions of integral cartridge-filter pool pump,[32] integral sand-filter pool pump,[33] and storable electric spa pump [34] in 10 CFR 431.462 do not conflict with the definitions of integral cartridge-filter pool pump motor, integral sand-filter pool pump motor, and storable electric spa pump motor in UL 1004–10:2020. Therefore, DOE has tentatively determined that these definitions in 10 CFR 431.462 do not need to be amended.

The definition of rigid electric spa pump motor in UL 1004–10:2020 states that the motor does not have a C-flange or square flange mounting and that it is labeled, designed, and marketed for use only in rigid electric spas as defined in 10 CFR 431.462, Subpart Y, Pumps. The definition of rigid electric spa pump in 10 CFR 431.462 specifies a different set of mounting requirements and does not include the requirement regarding end-use application.[35] DOE has tentatively determined that these differences could create conflict or confusion and that the UL 1004–10:2020 definition of rigid electric spa pump motor may cause confusion in that it may be interpreted as referring to a definition of ''rigid electric spa'' in 10 CFR 431.462, which does not currently exist. Hence, to align the definition of rigid electric spa pump in 10 CFR 431.462 with the definition of rigid electric spa pump motor in UL 1004–10:2020, DOE is proposing to amend the definition of rigid electric spa pump to specify that a rigid electric spa pump has a motor that does not have a C-flange or square flange mounting, and that is labeled, and designed and marketed for use only in rigid electric spas, in addition to the other criteria currently specified with the existing definition of rigid electric spa pump. DOE has not identified any pump motors with C-flange or square flange mounting that are marketed exclusively for spa pumps. As such, DOE has tentatively determined that this change in definition would not change the scope of pumps captured by the definition.

DOE requests comment on its proposed revision to the definition of rigid electric spa pump, particularly with regard to whether the language regarding C-flange or square flange mounting would change the scope of pumps captured by the definition.

The definition of waterfall pump motor in UL 1004–10:2020 states that the motor must have a maximum speed less than or equal to 1,800 revolutions per minute (''RPM'') and is designed and marketed for waterfall pump applications and labeled for use only with waterfall pumps. The definition of waterfall pump in 10 CFR 431.462 also specifies a maximum speed less than or equal to 1,800 RPM and additionally states that the certified maximum head must be less than or equal to 30.0 feet.[36] The specification of the maximum head in the definition of waterfall pump is not related to the motor component and therefore does not conflict or cause confusion with the definition of waterfall pump motor in UL 1004–10:2020. Therefore, DOE has tentatively determined the definition of waterfall pump in 10 CFR 431.462 does not need to be amended.

The definition of two-speed dedicated-purpose pool pump motor in UL 1004–10:2020 specifies that the pump motor is to be ''provided'' with a pool pump control or if without one, the pump cannot operate, among other criteria. The definition of two-speed dedicated-purpose pool pump in 10 CFR 431.462 specifies that the pump is to be ''distributed in commerce'' with a pool pump control or if without one, the pump cannot operate, among other criteria.[37] DOE understands that the phrases ''distributed in commerce'' and ''provided'' may be intended to convey the same meaning; however, the phrase ''distributed in commerce'' provides greater precision that better aligns with DOE's broader regulatory definitions and statutory language in EPCA.

[31] Dedicated-purpose pool pump is defined as comprising self-priming pool filter pumps, non-self-priming pool filter pumps, waterfall pumps, pressure cleaner booster pumps, integral sand-filter pool pumps, integral-cartridge filter pool pumps, storable electric spa pumps, and rigid electric spa pumps.

[32] Integral cartridge-filter pool pump is defined as a pump that requires a removable cartridge filter, installed on the suction side of the pump, for operation; and the cartridge filter cannot be bypassed.

[33] Integral sand-filter pool pump is defined as a pump distributed in commerce with a sand filter that cannot be bypassed.

[34] Storable electric spa pump is defined as a pump that is distributed in commerce with one or more of the following: (1) an integral heater; and (2) an integral air pump.

[35] Rigid electric spa pump is defined as an end suction pump that does not contain an integrated basket strainer or require a basket strainer for operation as stated in manufacturer literature provided with the pump and that meets the following three criteria: (1) is assembled with four through bolts that hold the motor rear endplate, rear bearing, rotor, front bearing, front endplate, and the bare pump together as an integral unit; (2) is constructed with buttress threads at the inlet and discharge of the bare pump; and (3) uses a casing or volute and connections constructed of a non-metallic material.

[36] Waterfall pump is defined as a pool filter pump with a certified maximum head less than or equal to 30.0 feet, and a maximum speed less than or equal to 1,800 rpm.

[37] Two-speed dedicated-purpose pool pump is defined as a dedicated-purpose pool pump that is capable of operating at only two different pre-determined operating speeds, where the low operating speed is less than or equal to half of the maximum operating speed and greater than zero, and must be distributed in commerce either: (1) with a pool pump control (*e.g.,* variable speed drive and user interface or switch) that is capable of changing the speed in response to user preferences; or (2) without a pool pump control that has the capability to change speed in response to user preferences, but is unable to operate without the presence of such a pool pump control.

Therefore, DOE has tentatively determined to maintain the wording ''distributed in commerce'' and make no amendments to the definition of two-speed dedicated-purpose pool pump in 10 CFR 431.462.

The definition of multi-speed dedicated-purpose pool pump motor in UL 1004–10:2002 contains notable differences compared to the definition of multi-speed dedicated-purpose pool pump at 10 CFR 431.462.[38] Table III.1 summarizes the differences between these definitions.

TABLE III.1—COMPARISON OF MULTI-SPEED DPPP AND MULTI-SPEED DPPP MOTOR DEFINITIONS

Multi-speed DPPP motor definition in UL 1004–10:2020	Multi-speed DPPP definition at 10 CFR 431.462
Allows for the motor to be provided without an on-board pool pump motor control that meets certain defined criteria, but includes a condition that the motor is ''unable to operate without the presence of'' such an on-board pool pump control.	Does not allow for the pump to be provided without an on-board pool pump motor control that meets certain defined criteria.
Uses the phrase ''provided'' with respect to the on-board pool pump control.	Uses the phrase ''distributed in commerce'' with respect to the on-board pool pump control.
Specifies that a multi-speed DPPP motor is not a variable-speed DPPP motor.	Does not specify any exclusion of variable-speed DPPP.

To align the multi-speed dedicated-purpose pool pump definition at 10 CFR 431.62 with the multi-speed dedicated-purpose pool pump motor definition in UL 1004–10:2020, DOE is proposing to amend the definition of multi-speed dedicated-purpose pool pump at 10 CFR 431.62 as follows: (1) explicitly allow for the pump to be distributed in commerce without an onboard pool pump control that meets the currently defined criteria, but include a condition that the pump is unable to operate without such an on-board pool pump motor control; and (2) explicitly specify that a multi-speed dedicated-purpose pool pump is not a variable-speed dedicated purpose pool pump. DOE has tentatively determined that these additions would further clarify the definition but would not be substantive changes (*i.e.,* would not change the scope of products currently on the market that meet this definition). DOE is also proposing to maintain the phrase ''distributed in commerce'' since ''distributed in commerce'' is more precise and better aligns with DOE's broader regulatory definitions and statutory language in EPCA than the phrase ''provided''.

Similarly, the definition of variable-speed dedicated-purpose pool pump motor in UL 1004–10:2002 contains notable differences compared to the definition of variable-speed dedicated-purpose pool pump at 10 CFR 431.462.[39] Table III.2 summarizes the differences between these definitions.

TABLE III.2—VARIABLE-SPEED DPPP AND DPPP MOTOR DEFINITIONS

Variable-speed DPPP motor definition in UL 1004–10:2020	Variable-speed DPPP definition at 10 CFR 431.462
Specifies the capability of operating at ''four or more discrete user- or pre-determined operating speeds.''.	Specifies the capability of operating at ''a variety of user-determined speeds.''
Does not contain any specifications regarding the separation of speeds	Requires that all the speeds are separated by at most 100 rpm increments over the operating range.
Requires that one of the operating speeds is the maximum operating speed and at least: (1) One of the operating speeds is 75% to 85% of the maximum operating speed; (2) One of the operating speeds is 45% to 55% of the maximum operating speed; and (3) One of the operating speeds is less than or equal to 40% of the maximum operating speed and greater than zero.	Requires that the lowest operating speed is less than or equal to one-third of the maximum operating speed and greater than zero.
Uses the phrase ''provided'' with respect to the user interface	Uses the phrase ''distributed in commerce'' with respect to the user interface.
Requires that the motor without a variable speed drive, and with or without a user interface, must be unable to operate without the presence of a variable speed drive.	No such specification regarding motor without variable speed drive.
Requires that any high-speed override capability shall be for a temporary period not to exceed one 24-hour cycle without resetting to default settings or resuming normal operating according to pre-programmed user preferences.	No such specification regarding high-speed override capability.

[38] Multi-speed dedicated-purpose pool pump is defined as a dedicated-purpose pool pump that is capable of operating at more than two discrete, predetermined operating speeds separated by speed increments greater than 100 rpm, where the lowest speed is less than or equal to half of the maximum operating speed and greater than zero, and must be distributed in commerce with an on-board pool pump control (*i.e.,* variable speed drive and user interface or programmable switch) that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times.

[39] Variable-speed dedicated-purpose pool pump is defined as a dedicated-purpose pool pump that is capable of operating at a variety of user-determined speeds, where all the speeds are separated by at most 100 rpm increments over the operating range and the lowest operating speed is less than or equal to one-third of the maximum operating speed and greater than zero. Such a pump must include a variable speed drive and be distributed in commerce either: (1) with a user interface that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times; or (2) without a user interface that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times, but is unable to operate without the presence of a user interface.

TABLE III.2—VARIABLE-SPEED DPPP AND DPPP MOTOR DEFINITIONS—Continued

Variable-speed DPPP motor definition in UL 1004–10:2020	Variable-speed DPPP definition at 10 CFR 431.462
Includes the following requirements regarding the daily run time schedule: (1) Any factory default setting for daily run time shall not include more hours at an operating speed above 55% of maximum operating speed than the hours at or below 55% of maximum operating speed; (2) If a motor is not provided with a factory default setting for daily run time schedule, the default operating speed after any priming cycle as defined in 10 CFR, Part 431, Subpart Y, (if applicable) shall be no greater than 55% of the maximum operating speed.	No such requirements regarding daily run time schedule.

To align the variable-speed dedicated-purpose pool pump definition at 10 CFR 431.62 with the variable-speed dedicated-purpose pool pump motor definition in UL 1004–10:2020, DOE is proposing to amend the definition of variable-speed dedicated-purpose pool pump at 10 CFR 431.62 as follows: (1) require the pump to be capable of operating at 4 or more speeds instead of ''a variety of'' speeds; (2) remove the specification that the speeds be no more than 100 RPM increments apart; (3) replace the specification that the lowest speed be one-third of the maximum operating speed with the speed requirements specified in the UL 1004–10:2020 definition; (4) maintain the phrase ''distributed in commerce'' rather than ''provided'', for the reasons previously described; (5) specify that with or without a user interface, the pump cannot operate without the variable speed drive; (6) add specifications regarding high-speed override capability consistent with the specifications provided in the UL 1004–10:2020 definition; and (7) add specifications regarding daily run time schedule consistent with the specifications provided in the UL 1004–10:2020 definition.

These amendments to the definition of variable-speed dedicate-purpose pool pump could change whether a DPPP is classified as being multi-speed or variable speed. However, because the DPPP test procedure for multi-speed and variable-speed dedicated-purpose pool pumps is the same, DOE has tentatively determined this would not result in any changes to measured values. In summary, DOE is proposing to amend the definition of variable-speed dedicated-purpose pool pump at 10 CFR 431.62 to align with the definition of variable-speed dedicated-purpose pool pump motor in UL 1004–10. This amendment would ensure that both the motor and the pump itself are categorized as variable-speed based on the same set of criteria.

DOE requests comments on whether any DPPPs currently on the market that meet the existing definition of variable-speed dedicated-purpose pool pump but that would not meet the proposed amended definition. DOE requests comment on whether the proposed amendments would change how any specific DPPP models are currently tested, and if so, how. In particular, DOE also requests comment on the necessity of including specifications related to high-speed override capability and daily run time schedule in the variable-speed dedicated-purpose pool pump definition.

Additionally, the terms ''designed and marketed'' [40] and ''dedicated-purpose pool pump motor total horsepower'' [41] are defined in both UL 1004–10:2020 and 10 CFR 431.462. The term ''designed and marketed'' is defined and used in the definition of pressure cleaner booster pump in 10 CFR 431.462, which is not defined in UL 1004–10:2020. Hence, DOE has tentatively determined that there is no conflict that requires amendment of the definition for designed and marketed. The definition of dedicated-purpose pool pump motor total horsepower in UL 1004–10:2020 specifies that total horsepower be ''calculated in accordance with the method provided in Section E.3.4 of appendix C of 10 CFR part 431, subpart Y, Pumps.'' This instruction is consistent with the requirements of the current DOE test procedure.[42] Therefore, to provide further consistency between UL 1004–10:2020 and DOE's test procedure, DOE proposes to specify in the definition of dedicated-purpose pool pump motor total horsepower in 10 CFR 431.462 that total horsepower is calculated in accordance with the method provided in section E.3.4 of DOE's DPPP test procedure.

UL 1004–10:2020 also defines the terms ''drive'' [43] and ''maximum operating speed''.[44] In 10 CFR 431.462, the term ''drive'' is used as part of the term ''variable speed drive,'' but is not defined separately. Similarly, the term ''maximum operating speed'' is used within the definitions of two-speed dedicated-purpose pool pump, variable-speed dedicated-purpose pool pump, and multi-speed dedicated-purpose pool pump in 10 CFR 431.462, but is not separately defined. To improve the comprehensiveness of the definitions in 10 CFR 431.462 and to further align with UL 1004–10:2020, DOE is proposing to add definitions for the terms ''drive'' and ''maximum operating speed'' consistent with how these terms are defined in UL 1004–10:2020.

UL 1004–10:2020 also defines the following terms that are not defined at 10 CFR 431.462: ''capacitor-start,'' ''induction-run,'' ''designed and/or marketed,'' ''factory default setting,'' and ''split phase.'' These terms are not used in the DPPP test procedure. Therefore, DOE has tentatively determined that there is no need to include them at 10 CFR 431.462 for DPPPs.

DOE requests comment on its proposed amendments to definitions in 10 CFR 431.462 for rigid electric spa pumps, m*ulti-speed dedicated-purpose pool pump,* variable-speed dedicated-

[40] ''Designed and marketed'' means that the equipment is designed to fulfill the indicated application and, when distributed in commerce, is designated and marketed for that application, with the designation on the packaging and any publicly available documents (*e.g.,* product literature, catalogs, and packaging labels). 10 CFR 431.462.

[41] Dedicated-purpose pool pump motor total horsepower means the product of the dedicated-purpose pool pump nominal motor horsepower and the dedicated-purpose pool pump service factor of a motor used on a dedicated-purpose pool pump based on the maximum continuous duty motor power output rating allowable for the motor's nameplate ambient rating and insulation class. (Dedicated-purpose pool pump motor total horsepower is also referred to in the industry as service factor horsepower or motor capacity.) 10 CFR 431.462.

[42] Section E.3.4 of appendix C specifies determining the dedicated-purpose pool pump motor total horsepower according to section E.3.4.1 of appendix C for dedicated-purpose pool pumps with single-phase AC motors or DC motors and section E.3.4.2 of appendix C for dedicated-purpose pool pumps with polyphase AC motors.

[43] Drive is defined in UL 1004–10:2020 as a power converter, such as a variable-speed drive or phase-converter.

[44] Maximum operating speed is defined in UL 1004–10:2020 as the rated full-load speed of a motor powered by a 60 Hz alternating current (AC) source.

purpose pool pump, and dedicated-purpose pool pump motor total horsepower. DOE requests comment on its proposal to add definitions in 10 CFR 431.462 for drive and maximum operating speed. DOE requests comment whether the proposed amendments would change how DPPP models are currently tested, and if so, how.

2. Integral Filters

DOE defines two types of DPPPs, integral cartridge-filter pool pump [45] and integral sand-filter pool pump,[46] as pool pumps for which the filter cannot be bypassed. 10 CFR 431.462. These two definitions depend on the defined term ''integral'' [47] and also on the currently undefined term ''bypassed.'' The definitions of these pump varieties do not explicitly provide whether removing the filtration media constitutes bypassing the filter. In the January 2022 TP RFI, DOE requested comment on whether it should define the term ''bypass'' and whether it should provide additional detail for the definition of the term ''integral.'' 87 FR 3457, 3459.

The PHTA commented that the term ''integral'' was specified for pumps in which the filtration apparatus cannot be bypassed so that only the motor efficiency can be isolated for testing. (PHTA, No. 6, p. 13) The PHTA added that based on industry experience, use of the term ''bypass'' in the definition of integral is easy to understand and labs do not have an issue in determining whether a motor can be bypassed from the filtration medium for testing. (PHTA, No. 6, p. 13)

Considering this comment from PHTA, DOE has tentatively determined that the definitions of integral, integral cartridge-filter pool pump, and integral sand-filter pool pump are sufficient in identifying whether a pool pump constitutes an integral cartridge-filter pool pump or integral sand-filter pool pump, and that defining the term ''bypassed'' or any other associated terminology is not necessary.

DOE requests comments on its tentative determination that amendments to the definitions of integral, integral cartridge-filter pool pump, and integral sand-filter pool pump are not necessary, and that a new definition for the term ''bypassed'' is not necessary.

3. Pool Pump Timers

The energy conservation standards for integral cartridge-filter pool pumps and integral sand-filter pool pumps at 10 CFR 431.465 require that each pump that is manufactured starting on July 19, 2021 must be distributed in commerce with a pool pump timer that is either integral to the pump or a separate component shipped with the pump. 10 CFR 431.465(g). The term ''pool pump timer'' is defined as a pool pump control that automatically turns off a DPPP after a run-time of no longer than 10 hours. 10 CFR 431.462.

In the January 2022 TP RFI, DOE requested comment on whether it should provide additional detail in the definitions of pool pump timers and integral filter housings regarding the requirements of the pool pump timer. 87 FR 3457, 3459. The PHTA commented that the definition of ''pool pump timer'' could be further clarified to specify that it only applies to integral cartridge filter pumps and integral sand filter pumps. (PHTA, No. 6, p. 12)

The term ''pool pump timer,'' aside from being defined in 10 CFR 431.462, is referenced by DOE only at 10 CFR 431.465(g). As described, the design requirements specified at 10 CFR 431.465(g) pertain only to integral cartridge filter pool pumps and integral sand filter pool pumps. Although the term is only used by DOE in reference to integral cartridge filter pool pumps and integral sand filter pool pumps, DOE has tentatively concluded that it is not necessary to limit the definition of pool pump timer to only these two types of DPPPs. Therefore, DOE has tentatively determined that further clarification of the definition of pool pump timer is not needed

D. Test Method for Pressure Cleaner Booster Pumps

The current DOE test procedure requires testing pressure cleaner booster pumps at one load point specified for a flow of 10.0 gpm, a head of greater than or equal to 60 feet, and the lowest speed capable of meeting the specified flow and head values. (See Table 1 of appendix C.)

The CA IOUs commented in response to the January 2022 TP RFI that DOE should specify a low-flow and high-flow operating test point for the pressure cleaner booster pumps to account for installations where the pump is easily able to overcome the head pressure to support the pressure cleaner. The CA IOUs commented that this method would enable DOE to consider more representative field operation of these products when estimating national impact savings. The CA IOUs further commented that a study it previously presented to DOE [48] had reported that pressure cleaner booster pumps require 8 or less gpm between 32 to 51 feet of head, meaning DOE's test point at 60 feet of head would be higher than needed for some installations. The CA IOUs stated that pressure cleaners use a relief/bypass valve to reduce the cleaner wheel operating speed to the desired conditions (*i.e.,* 30 RPM) and, therefore, the additional energy to the unit is not providing consumer amenity. The CA IOUs also provided an example of an instrumented pool that has a measured total system head of 13 feet at a filtration flow rate of 31.7 gpm and noted that the DOE test procedure assumes pressure cleaner booster pump head requirements will not be below 60 feet. (CA IOUs, No. 10, p. 4–5)

DOE notes that the DPPP Working Group when providing their 2015 recommendations for the DPPPs test procedure had recommended a single, fixed load point of 90 feet of head at maximum speed for pressure cleaner booster pumps because any given pressure-side pool cleaner application is typically a single, fixed load point. (Docket No. EERE–2015–BT–STD–0008, No. 51, Recommendations #6); 81 FR 64580, 64611. This test point was proposed as sufficiently representative of typical cleaner booster pump operation and achievable by the models available at that time, but the DPPP Working Group noted field conditions were variable and operating conditions would depend on application of the pump. 81 FR 64580, 64611. In discussions with the DPPP Working Group, the CA IOUs had also presented data supporting the potential for variable-speed pressure cleaner booster pumps to reduce speed and provide the requisite flow rate and cleaner operating speed at lower head values. (Docket No. EERE–2015–BT–STD–0008, CA IOUs, No. 69); 81 FR 64580, 64611–64612. To better capture the potential for variable performance of pressure cleaner booster pumps, including variable speed pressure cleaner booster pumps, the DPPP Working Group revised its original recommendation for testing at a fixed head of 90 feet, instead suggesting in their June 2016 recommendations testing at a single load point of 10 gpm at the minimum speed that results in a head value at or above 60 feet, which was identified as the minimum optimum pool design. (Docket No.

[45] Integral cartridge-filter pool pump means a pump that requires a removable cartridge filter, installed on the suction side of the pump, for operation; and the cartridge filter cannot be bypassed.

[46] Integral sand-filter pool pump means a pump distributed in commerce with a sand filter that cannot be bypassed.

[47] Integral means a part of the device that cannot be removed without compromising the device's function or destroying the physical integrity of the unit. 10 CFR 431.462.

[48] *www.regulations.gov/document/EERE-2015-BT-STD-0008-0061.*

2015–BT–STD–0008, No. 82, Recommendation #8 at p. 4–5) DOE agreed with this recommendation but proposed in the 2016 TP NOPR to more precisely specify the load point as a flow rate of 10.0 gpm and a head value at or above 60.0 feet. 81 FR 64580, 64612. In the August 2017 TP Final Rule, DOE stated that the DPPP Working Group had noted that the suction-side pressure cleaner apparatus typically recommends a specific flow rate that allows the equipment to operate correctly and had accordingly selected 10 gpm. 82 FR 36858, 36885–36886. Further, once that flow and head value are achieved, the pressure cleaner booster pumps will operate at only that one load point. *Id.*

The CA IOUs have not presented significant information that was not considered by the DPPP Working Group, other than a measurement from a single instrumented pool, that indicates that some pools may have a head below 60 feet. The current test point of 10 gpm at 60 feet or above was selected after considering the CA IOUs' study, which measured variable speed pump operation at 54 feet of head in a pool which was noted to have the optimum 1.5 inch piping and minimum hose length.[49] In discussing that study, the CA IOUs also reported that the curves for the pressure cleaners (of which there were only three) showed a requirement of 8 or less gpm between 32 to 51 feet of head but ignore the pipe in between.[50] DOE has not identified or been provided with any new technical justification for allowing testing of pressure cleaner booster pumps below 60 feet of head, or for determining that 10 gpm is not a reasonable minimum flow rate. The current test method allows for potential variable-speed pressure cleaner booster pumps to operate at lower speed and lower head value than a single speed pump while still providing the necessary 10 gpm. Therefore, DOE has tentatively determined not to amend the test method for pressure cleaner booster pumps. DOE also notes that it is typical for an energy use analysis to account for a variety of installations other than that which the test procedure identifies as representative; as such, the DOE test procedure both allows differentiation in WEF for variable speed pressure cleaner booster pumps and does not limit any potential related energy conservation standards analysis.

DOE requests comments on its tentative determination not to amend the test method for pressure cleaner booster pumps, and specifically any additional field data indicating appropriate head and flow values for testing these pumps.

E. Removing Appendix B

As discussed, DOE's energy conservation standards are based on the WEF metric. However, as discussed in the 2017 rulemaking, the DPPP Working Group noted the importance of the energy factor (''EF'') metric in making product selections for specific applications or making energy saving calculations in support of utility programs. 82 FR 36858, 36895. To prevent confusion by allowing EF as an optional alternative metric, DOE established both appendix B, which specified test procedures for determining both EF and WEF, and appendix C which specified test procedures only for determining WEF. DOE required manufacturers to make representations with respect to energy use or efficiency of DPPPs based on appendix B between February 5, 2018 and July 19, 2021. DOE also specified that any optional representations of EF must be accompanied by a representation of WEF. 82 FR 36858, 36896. DOE then required that any representations made on or after July 19, 2021 with respect to the energy use or efficiency of dedicated-purpose pool pumps subject to testing pursuant to 10 CFR 431.464(b) be made in accordance with the results of testing pursuant to appendix C, which specifies test procedures only for the WEF metric. *Id.*

As a result of the time limit applicable to appendix B, representations of EF are no longer relevant to DPPPs. Therefore, DOE proposes to remove appendix B as obsolete and to rename the current appendix C as appendix B. As such, updates proposed in this NOPR that apply to the current appendix C would be implemented as new appendix B.

F. Reporting

Manufacturers, including importers, must use product-specific certification templates to certify compliance to DOE. For DPPPs, the certification template reflects the general certification requirements specified at 10 CFR 429.12 and the product-specific requirements specified at 10 CFR 429.59. DOE is not proposing to amend the product-specific certification requirements for these products.

G. Test Procedure Costs and Harmonization

1. Test Procedure Costs and Impact

In this NOPR, DOE proposes to amend the existing test procedure for DPPPs by (1) codifying DOE's current enforcement policy pertaining to DPPPs that cannot be appropriately tested by the DOE test procedure; (2) updating references to industry test standards to reflect current industry practices; (3) aligning DOE's DPPP definitions with DOE's corresponding DPPP motor definitions; and (4) removing the current test procedure at appendix B, which is obsolete. DOE has tentatively determined that these proposed amendments would not impact testing costs.

DOE is proposing to update the currently referenced 2014 version of HI 40.6–2014 to the 2021 version and the currently referenced 2015 version of NSF/ANSI 50 to the 2020 version. As discussed in section III.B of this NOPR, DOE has determined that updates to the latest versions of these industry standards will not change measured values.

DOE is proposing to remove the current appendix B, which provides instruction on calculating EF, a metric that is not required by DOE standards or certification (see section I.A of this NOPR). Hence, this change will not have any impact on measured values of WEF, the currently required metric.

Finally, DOE is proposing to align the DOE's DPPP definitions with DOE's DPPP motor definition (see section III.C.1 of this NOPR). As discussed, DOE has tentatively concluded that these proposed amendments to definitions will not impact how manufacturers are currently testing DPPPs.

In summary, DOE has tentatively determined that the proposed amendments would not impact the representations of DPPPs energy efficiency or energy use. DOE has tentatively determined that manufacturers would be able to rely on data generated under the current test procedure, should the proposed amendments be finalized. As such, DOE does not expect retesting of DPPPs would be required solely as a result of DOE's adoption of the proposed amendments to the test procedure.

DOE requests comment on the impact and associated costs of the proposed amendments in this NOPR.

2. Harmonization With Industry Standards

DOE's established practice is to adopt relevant industry standards as DOE test procedures unless such methodology

[49] Docket No. EERE–2015–BT–STD–0008, No. 100, p. 187–188.

[50] *Id.*

would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA), or estimated operating costs of that product during a representative average use cycle. 10 CFR 431.4; Section 8(c) of appendix A of 10 CFR part 430 subpart C. In cases where the industry standard does not meet EPCA statutory criteria for test procedures, DOE will make modifications through the rulemaking process to these standards as the DOE test procedure.

The test procedures for DPPPs at 10 CFR 431.464(b) and appendix C to subpart Y of part 431 incorporates by reference HI 40.6–2014, which specifies the test conditions and methods for testing the efficiency of pumps, and NSF/ANSI 50–2015, which specifies how to determine the self-priming capability of a pump—information needed to ensure the appropriate test procedure is used for DPPP self-priming and non-self-priming pumps. DOE is proposing to update HI 40.6–2014 to its latest 2021 version and NSF/ANSI 50–2015 to its latest 2020 NSF/ANSI/CAN 50 version. The industry standards DOE proposes to incorporate by reference via amendments described in this proposed rule are discussed in further detail in section IV.M.

DOE requests comments on the benefits and burdens of the proposed updates and additions to industry standards referenced in the test procedure for DPPPs.

H. Compliance Date

EPCA prescribes that if DOE amends a test procedure, all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with that amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6314(d)(1)) If DOE were to publish an amended test procedure, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6314(d)(2)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this proposed regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this proposed regulatory action does not constitute a ''significant regulatory action'' under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *www.energy.gov/gc/office-general-counsel.*

DOE notes that the Regulatory Flexibility Act requires analysis of, in particular, ''small entities'' that might be affected by the rule. For the DPPP manufacturing industry, the Small Business Administration (''SBA'') has set a size threshold, which defines those entities classified as ''small businesses'' for the purpose of the statute. DOE used the SBA's size standards to determine whether any small entities would be required to comply with the rule. The size standards are codified at 13 CFR part 121. The standards are listed by North American Industry Classification System (''NAICS'') code and industry description and are available at *www.sba.gov/document/support-table-size-standards.*

DPPP manufacturers are classified under NAICS 333914, ''Measuring, Dispensing, and Other Pumping Equipment Manufacturing.'' The SBA sets a threshold of 750 employees or less for an entity to be considered as a small business for this category. To determine the number of DPPP manufacturers that are small businesses and might be differentially affected by the rule, DOE reviewed these data to determine whether the entities met the SBA's definition of a small business manufacturer of DPPPs and then screened out companies that do not offer equipment covered by this rulemaking, do not meet the definition of a ''small business,'' are foreign-owned and operated, or are owned by another company.

DOE conducted a focused inquiry into small business manufacturers of the DPPPs covered by this rulemaking. DOE used available public information to identify potential small manufacturers.

DOE accessed the Compliance Certification Database,[51] California Energy Commission's certification database,[52] and ENERGY STAR's product database [53] to create a list of companies that import or otherwise manufacture the DPPPs covered by this proposal. DOE identified a total of 32 companies that manufacturer or sell DPPPs covered by this proposal in the United States. Of these companies, 15 are original equipment manufacturers (''OEMs'') that manufacturer these covered products; the other 17 companies are re-branders or private labelers that are not OEMs and out-source the production of the DPPPs they sell to other manufacturers. Of the 15 OEMs, 3 meet SBA's definition of a small business.

As discussed in section III.G.1 of this NOPR, DOE tentatively determined that the proposed amendments would not impact representations of DPPP energy efficiency or energy use and that DPPP manufacturers would be able to rely on data generated under the current test procedure, should the proposed amendments be finalized. Based on this initial determination, DOE tentatively determines that no DPPP manufacturers, including those that meet SBA's definition of a small business, would incur any additional costs due solely to this proposed test procedure, if finalized. Therefore, DOE initially concludes that the impacts of the proposed test procedure amendments proposed in this NOPR would not have a ''significant economic impact on a substantial number of small entities,'' and that the preparation of an IRFA is not warranted. DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of DPPPs must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including DPPPs. (*See generally* 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

DOE is not proposing to amend the certification or reporting requirements for DPPP in this NOPR.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this NOPR, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for DPPPs. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, appendix A to subpart D, A5 and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial, direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

[51] U.S. Department of Energy Compliance Certification Database, available at: *www.regulations.doe.gov/certification-data.*

[52] California Energy Commission's Modernized Appliance Efficiency Database System, available at: *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx.*

[53] ENERGY STAR's product database, available at: *www.energystar.gov/products/pool_pumps.*

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *energy.gov/gc/office-general-counsel*. DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), that this proposed regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf*. DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of DPPPs is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; ''FEAA'') Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for DPPPs would incorporate testing methods contained in certain sections of the following commercial standards: (1) HI 40.6–2021, ''Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing'' and (2) NSF/ANSI/CAN 50—2020, ''Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities.''

DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review). DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

HI 40.6–2021 is an industry-accepted test standard that provides test conditions and methods for measuring the efficiency of pumps. The test procedure proposed in this NOPR references various sections of HI 40.6–2021 that address test conditions and methods. This test standard is reasonably available from the Hydraulic Institute (*www.pumps.org*).

NSF/ANSI/CAN 50–2020 is an industry-accepted test standard that provides test methods for determining self-priming capabilities of pumps. The

test procedure proposed in this NOPR references various sections of HI 40.6–2021 that address test conditions and methods. This test standard is reasonably available from the NSF Bookstore (*www.techstreet.com/nsf*), ANSI (*www.ansi.org*) or the Standards Council of Canada (*www.scc.ca/en/welcome-standards-store*).

CSA C747–2019 is an industry-accepted test standard that provides test methods for measuring the efficiency of small motors. The test procedure proposed in this NOPR references various sections of CSA C747–2019 that address test conditions and methods. This test standard is reasonably available from ANSI (*www.ansi.org*) or CSA Group (*www.csagroup.org*).

The following standards were previously approved for incorporation by reference in the locations where they appear in the regulatory text: IEEE 114–2010, and IEEE 113–1985. The following standard was previously approved for incorporation by reference in a location which is being redesignated: HI 41.5–2022.

V. Public Participation

A. Participation in the Webinar

The time and date of the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=67*. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this proposed rule, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit to *ApplianceStandardsQuestions@ee.doe.gov*. Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this proposed rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

DOE requests persons selected to make an oral presentation to submit an advance copy of their statements at least two weeks before the webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar/public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this proposed rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE) before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the webinar/public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this proposed rule. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule.[54] Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be

[54] DOE has historically provided a 75-day comment period for test procedure NOPRs pursuant to the North American Free Trade Agreement, U.S.-Canada-Mexico (''NAFTA''), Dec. 17, 1992, 32 I.L.M. 289 (1993); the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (1993) (codified as amended at 10 U.S.C.A. 2576) (1993) (''NAFTA Implementation Act''); and Executive Order 12889, ''Implementation of the North American Free Trade Agreement,'' 58 FR 69681 (Dec. 30, 1993). However, on July 1, 2020, the Agreement between the United States of America, the United Mexican States, and the United Canadian States (''USMCA''), Nov. 30, 2018, 134 Stat. 11 (*i.e.,* the successor to NAFTA), went into effect, and Congress's action in replacing NAFTA through the USMCA Implementation Act, 19 U.S.C. 4501 *et seq.* (2020), implies the repeal of E.O. 12889 and its 75-day comment period requirement for technical regulations. Thus, the controlling laws are EPCA and the USMCA Implementation Act. Consistent with EPCA's public comment period requirements for consumer products, the USMCA only requires a minimum comment period of 60 days. Consequently, DOE now provides a 60-day public comment period for test procedure NOPRs.

included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (''faxes'') will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comment on its preliminary determination not to propose a test procedure specific to DPPPs with hydraulic output power greater than 2.5 hhp. DOE also requests data that would allow it to develop such a test procedure if it was determined to be warranted, including distribution of commercial pool sizes and piping, distribution of head and flow requirements across applications in consideration of current health and safety codes, and distribution of single speed and variable speed installations.

(2) DOE requests comment on its preliminary determination not to propose a test procedure specific to DPPPs currently subject to the DPPP Enforcement Policy. DOE also requests data related to the applications these DPPPs serve including pool size, piping size, and minimum head and flow requirements. DOE also requests any data and information related to development of a curve E, as well data indicating how such a curve was determined (or could be determined) to be representative of this set of pumps. DOE further requests comment on its proposal to amend the Scope section of the test procedure to explicitly exclude such pumps from the scope of the test procedure.

(3) DOE requests comments on the proposal to incorporate by reference HI 40.6–2021, NSF/ANSI/CAN 50–2020, and CSA C747–2019 for appendix C.

(4) DOE requests comment on its proposed revision to the definition of rigid electric spa pump, particularly with regard to whether the language regarding C-flange or square flange mounting would change the scope of pumps captured by the definition.

(5) DOE requests comments on whether any DPPPs currently on the market that meet the existing definition of variable-speed dedicated-purpose pool pump but that would not meet the proposed amended definition. DOE requests comment on whether the proposed amendments would change how any specific DPPP models are currently tested, and if so, how. In particular, DOE also requests comment on the necessity of including specifications related to high-speed override capability and daily run time schedule in the variable-speed dedicated-purpose pool pump definition.

(6) DOE requests comment on its proposed amendments to definitions in 10 CFR 431.462 for rigid electric spa pumps, multi-speed dedicated-purpose pool pump, variable-speed dedicated-purpose pool pump, and dedicated-purpose pool pump motor total horsepower. DOE requests comment on its proposal to add definitions in 10 CFR 431.462 for drive and maximum operating speed. DOE requests comment whether the proposed amendments would change how DPPP models are currently tested, and if so, how.

(7) DOE requests comments on its tentative determination that amendments to the definitions of integral, integral cartridge-filter pool pump, and integral sand-filter pool pump are not necessary, and that a new definition for the term ''bypassed'' is not necessary.

(8) DOE requests comments on its tentative determination not to amend the test method for pressure cleaner booster pumps, and specifically any additional field data indicating appropriate head and flow values for testing these pumps.

(9) DOE requests comment on the impact and associated costs of the proposed amendments in this NOPR.

(10) DOE requests comments on the benefits and burdens of the proposed updates and additions to industry

standards referenced in the test procedure for DPPPs.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Incorporation by reference, Reporting and recordkeeping requirements.

10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation test procedures, Incorporation by reference, and Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on October 28, 2022, by Francisco Alejandro Moreno, Acting 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 November 2, 2022.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 431 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

* * * * *

■ 2. Amend § 429.4 by revising paragraph (d)(1) to read as follows:

§ 429.4 Materials incorporated by reference.

* * * * *

(d) * * *

(1) HI 40.6–2021, *Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing,* approved February 17, 2021; IBR approved for § 429.134.

* * * * *

■ 3. Amend § 429.134 by:

■ a. Removing in paragraph (i)(2)(iv)(A)(1), the text ''HI 40.6–2014–B'', wherever it appears, and adding, in its place, the text, ''HI 40.6–2021'';

■ b. Removing in paragraph (i)(2)(iv)(A)(2), the text ''HI 40.6–2014–B'', wherever it appears, and adding, in its place, the text, ''HI 40.6–2021''; and

■ c. Adding paragraph (i)(2)(v).

The addition reads as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(i) * * *

(2) * * *

(v) To verify the flow rate of a DPPP model at 50 feet of head, the flow rate in gallons per minute (gpm) at 50 feet of head will be determined pursuant to Section 40.6.5.5.1, ''Test procedure'' and Section 40.6.6.3, ''Performance curve'' of HI 40.6–2021 (incorporated by reference, see § 429.4). In cases where the flow rate of 50 feet of head cannot be directly determined due to the entirety of the performance curve (out to the model's maximum flow rate of greater than or equal to 200 gpm) exceeding 50 feet of head, DOE will determine that the DPPP model has a flow rate of greater than or equal to 200 gpm at 50 feet of head. DOE will use the mean of the determined flow rate at 50 feet of head (either the determined flow rate for a single unit sample or the average of the determined flow rates for a multiple unit sample) to determine the applicable standard level, if any, for purposes of compliance.

* * * * *

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 4. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 5. Amend § 431.462 by:

■ a. Revising the definition for ''Dedicated-purpose pool pump motor total horsepower'';

■ b. Adding in alphabetical order the definition for ''Drive,'' and ''Maximum operating speed''; and

■ c. Revising the definitions for ''Multi-speed dedicated-purpose pool pump,'' ''Rigid electric spa pump,'' and ''Variable-speed dedicated-purpose pool pump.''

The revisions and additions read as follows:

§ 431.462 Definitions.

* * * * *

Dedicated-purpose pool pump motor total horsepower means the product of the dedicated-purpose pool pump nominal motor horsepower and the dedicated-purpose pool pump service factor of a motor used on a dedicated-purpose pool pump based on the maximum continuous duty motor power output rating allowable for the motor's nameplate ambient rating and insulation class and calculated in accordance with the method provided in section E.3.4 of appendix B to subpart Y of this part. (Dedicated-purpose pool pump motor total horsepower is also referred to in the industry as service factor horsepower or motor capacity.)

* * * * *

Drive is a power converter, such as a variable-speed drive or phase-converter.

* * * * *

Maximum operating speed is the rated full-load speed of a motor powered by a 60 Hz alternating current (AC) source.

* * * * *

Multi-speed dedicated-purpose pool pump means a dedicated-purpose pool pump that is not a variable-speed dedicated-purpose pool pump as defined in this section and that is capable of operating at more than two discrete, pre-determined operating speeds separated by speed increments greater than 100 rpm, where the lowest speed is less than or equal to half of the maximum operating speed and greater than zero, and must be distributed in commerce either:

(1) With an on-board pool pump control (*i.e.,* variable speed drive and user interface or programmable switch) that changes the speed in response to

pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times; or

(2) Without an onboard pool pump control (*i.e.,* variable speed drive and user interface or programmable switch) that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times, but is unable to operate without the presence of such pool pump control.

* * * * *

Rigid electric spa pump means an end suction pump that has a motor that does not have a C-flange or square flange mounting, and that is labeled, and designed and marketed for use only in rigid electric spas and does not contain an integrated basket strainer or require a basket strainer for operation as stated in manufacturer literature provided with the pump, and that meets the following three criteria:

(1) Is assembled with four through bolts that hold the motor rear endplate, rear bearing, rotor, front bearing, front endplate, and the bare pump together as an integral unit;

(2) Is constructed with buttress threads at the inlet and discharge of the bare pump; and

(3) Uses a casing or volute and connections constructed of a non-metallic material.

* * * * *

Variable-speed dedicated-purpose pool pump means a dedicated-purpose pool pump that:

(1) Is capable of operating at four or more discrete user- or pre-determined operating speeds, where one of the operating speeds is the maximum operating speed and at least:

(a) One of the operating speeds is 75% to 85% of the maximum operating speed;

(b) One of the operating speeds is 45% to 55% of the maximum operating speed; and

(c) One of the operating speeds is less than or equal to 40% of the maximum operating speed and greater than zero.

(2) Includes a variable speed drive and is distributed in commerce either:

(a) With a user interface that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times;

(b) Without a user interface that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times, but is unable to operate without the presence of a user interface; or

(3) With or without user interface, provided that the motor is unable to operate without the presence of a variable speed drive, and

(3) Also meets the following requirements:

(a) Any high-speed override capability shall be for a temporary period not to exceed one 24-hour cycle without resetting to default settings or resuming normal operation according to pre-programmed user preferences; and

(b) Daily run time schedule:

(i) Any factory default setting for daily run time schedule shall not include more hours at an operating speed above 55% of maximum operating speed than the hours at or below 55% of the maximum operating speed;

(ii) If a motor is not provided with a factory default setting for daily run time schedule, the default operating speed after any priming cycle (if applicable) shall be no greater than 55% of the maximum operating speed.

* * * * *

■ 6. Amend § 431.463 by:

■ a. Revising paragraph (b)(1);

■ b. Removing paragraph (d)(4);

■ c. Redesignating paragraphs (d)(5) and (6) as (d)(4) and (5), respectively;

■ d. Revising newly redesignated paragraph (d)(4);

■ e. In newly redesignated paragraph (d)(5), removing the text ''appendix D'' and adding in its place the text ''appendix C''; and

■ f. Revising paragraph (g)(1).

The revisions read as follows:

§ 431.463 Materials incorporated by reference.

* * * * *

(b) * * *

(1) CSA C747–2009 (Reaffirmed 2019), (''CSA C747–09 (R2019)''), ''Energy efficiency test methods for small motors,'' CSA reaffirmed 2019, IBR approved for appendix B to this subpart.

* * * * *

(d) * * *

(4) HI 40.6–2021, *Hydraulic Institute Standard for Methods for Rotodynamic Pump Efficiency Testing,* approved February 17, 2021; IBR approved for 431.464 and appendices B and C to this subpart.

* * * * *

(g) * * *

(1) NSF/ANSI/CAN 50–2020, ''Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs, and Other Recreational Water Facilities,'' ANSI-approved October 21, 2020; IBR approved for § 431.462 and appendix B to this subpart.

* * * * *

§ 431.462 [Amended]

■ 7. In § 431.462, amend the definitions for ''Non-self-priming pool filter pump'' and ''Self-priming pool filter pump'' by removing the text ''NSF/ANSI 50–2015'' and adding, in its place, the text ''NSF/ANSI/CAN 50–2020''.

■ 8. Amend § 431.464 by revising paragraphs (b)(1)(iii), (b)(2), and (c)(2) to read as follows:

§ 431.464 Test procedure for the measurement of energy efficiency, energy consumption, and other performance factors of pumps.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(A) Submersible pumps;

(B) Self-priming and non-self-priming pool filter pumps with hydraulic output power greater than or equal to 2.5 horsepower; and

(C) Dedicated purpose pools pumps that meet all of the following three criteria:

(*1*) The orifice on the pump body that accepts suction side plumbing connections has an inner diameter of greater than 2.85 inches;

(*2*) The pump has a measured performance of ≥200 gallons per minute (gpm) at 50 feet of head as determined in accordance with section 40.6.5.5.1, ''Test procedure'' and section 40.6.6.3, ''Performance curve'' of HI 40.6–2021 (incorporated by reference, see § 431.463); and

(*3*) The pump is marketed exclusively for commercial applications.

(2) *Testing and calculations.* Determine the weighted energy factor (WEF) using the test procedure set forth in appendix B of this subpart.

(c) * * *

(2) *Testing and calculations.* Determine the circulator energy index (CEI) using the test procedure set forth in appendix C of this subpart Y.

Appendix B to Subpart Y of Part 431 [Removed]

■ 9. Appendix B to subpart Y of part 431 is removed.

Appendix C to Subpart Y of Part 431 [Redesignated as Appendix B]

■ 10. Appendix C to Subpart Y of Part 431 is redesignated as ''Appendix B to Subpart Y of Part 431'' and revised to read as follows:

Appendix B to Subpart Y of Part 431—Uniform Test Method for the Measurement of Energy Efficiency of Dedicated-Purpose Pool Pumps

Note: Beginning [*Date 180 days after date of publication in the* **Federal Register**], any representations made with respect to the energy use or efficiency of dedicated-purpose pool pumps subject to testing pursuant to 10 CFR 431.464(b)(2) must be made in

accordance with the results of testing pursuant to this appendix.

1.0 Incorporation by Reference

DOE incorporated by reference in § 431.463, the entire standard for: CSA C747–09 (R2019), HI 40.6–2021, IEEE 114–2010, IEEE 113–1985, and NSF/ANSI/CAN 50–2020; however, only enumerated provisions of CSA C747–09 (R2019), HI 40.6–2021, IEEE 114–2010, IEEE 113–1985, and NSF/ANSI/CAN 50–2020 are applicable to this appendix, as follows:

1.1 CSA C747–09 (R2019)

(a) Section 5 ''General test requirements'', and Section 6 ''Test Method'' as referenced in sections 6.3.2.1.2 and 6.3.2.2.2 of this appendix.

(b) [Reserved]

1.2 HI 40.6–2021

(a) Section 40.6.2 ''Terms and definitions, as referenced in section 2.1 of this appendix.

Section 40.6.3 ''Pump efficiency testing'', as referenced in sections 4.1, 5.1, and 7.1.4 of this appendix, including.

(i) Table 40.6.3.2.2 ''Permissible amplitude of fluctuation as a percentage of mean values of quantity being measured at any test point'' as referenced in sections 5.1 and 7.1.4 of this appendix.

(ii) Table 40.6.3.2.3 ''Maximum permissible measurement device uncertainty'' as referenced in section 3.1 of this appendix.

(b) Section 40.6.4 ''Considerations when determining the efficiency of certain pumps'',. as referenced in sections 2.1 and 4.1 of this appendix.

(c) Section 40.6.5.4 ''Test arrangements'' as referenced in sections 2.1 and 4.1 of this appendix.

(d) Section 40.6.5.5 ''Test conditions'' as referenced in sections 2.1, 4.1, and 5.2 of this appendix (e) Section 40.6.6.2 ''Pump efficiency'' and Section 40.6.6.3 ''Performance curve'' as referenced in section 2.1 of this appendix.

(f) Appendix A, ''Test arrangements (normative)'' as referenced in section 4.1 of this appendix.

(g) Appendix C, ''Measurement equipment (normative)'' as referenced in section 3.1 of this appendix.

(h) Appendix D, ''Suitable time periods for calibration of test instruments (normative)'', including Table D.1, ''Default instrument recalibration periods'' as referenced in section 3.2 of this appendix.

(i) A.3.1.3.1 ''Correction for height difference'' as referenced in section 7.1.2.1 of this appendix.

1.3 IEEE 114–2010

(a) Section 3.2 ''Test with load'', Section 4 ''Testing facilities'', Section 5.2 ''Mechanical measurements'', Section 5.3 ''Temperature measurements'', and Section 6 ''Tests'' as referenced in section 6.3.2.1.1 of this appendix.

(b) [Reserved]

1.4 IEEE 113–1985

(a) Section 3.1 ''Instrument Selection Factors'', Section 3.4 ''Power Measurement'', Section 3.5 ''Power Sources'', Section 4.1.2 ''Ambient Air'', Section 4.1.4 ''Direction of Rotation'', Section 5.4.1 ''Reference Conditions'', and Section 5.4.3.2 ''Dynomometer or Torquemeter Method'' as referenced in section 6.3.2.2.1 of this appendix.

(b)

1.5 NSF/ANSI/CAN 50–2020

(a) Section N–3.3, ''Self-priming capability'' as referenced in sections 7.1, 7.1.1, 7.1.4, and 7.1.5 of this appendix.

(b) [Reserved]

2.0 General

2.1 Test Method. To determine the weighted energy factor (WEF) for dedicated-purpose pool pumps, perform ''wire-to-water'' testing in accordance with HI 40.6–2021, except section 40.6.4.1, ''Vertically suspended pumps''; section 40.6.4.2, ''Submersible pumps''; section 40.6.5.5, ''Test conditions''; section 40.6.5.5.2, ''Speed of rotation during test''; section 40.6.6.2, ''Pump efficiency''; and section 40.6.6.3, ''Performance curve''; with the modifications and additions as noted throughout the provisions below. Do not use the test points specified in section 40.6.5.5.1, ''Test procedure'' of HI 40.6–2021 and instead use those test points specified in section 5.3 of this appendix for the applicable dedicated-purpose pool pump variety and speed configuration. When determining overall efficiency, best efficiency point, or other applicable pump energy performance information, section 40.6.5.5.1, ''Test procedure''; section 40.6.6.2, ''Pump efficiency''; and section 40.6.6.3, ''Performance curve'' must be used, as applicable. For the purposes of applying this appendix, the term ''volume per unit time,'' as defined in Section 40.6.2, ''Terms and definitions,'' of HI 40.6–2021 shall be deemed to be synonymous with the term ''flow rate'' used throughout that standard and this appendix.

2.2 Calculations and Rounding. All terms and quantities refer to values determined in accordance with the procedures set forth in this appendix for the rated pump. Perform all calculations using raw measured values without rounding. Round WEF, maximum head, vertical lift, and true priming time values to the tenths place (*i.e.,* 0.1) and rated hydraulic horsepower to the thousandths place (*i.e.,* 0.001). Round all other reported values to the hundredths place unless otherwise specified.

3.0 Measurement Equipment

3.1 For the purposes of measuring flow rate, speed of rotation, temperature, and pump power output, the equipment specified in HI 40.6–2021 Appendix C necessary to measure head, speed of rotation, flow rate, and temperature must be used and must comply with the stated accuracy requirements in HI 40.6–2021 Table 40.6.3.2.3, except as specified in sections 3.1.1 and 3.1.2 of this appendix. When more than one instrument is used to measure a given parameter, the combined accuracy, calculated as the root sum of squares of individual instrument accuracies, must meet the specified accuracy requirements.

3.1.1 Electrical measurement equipment for determining the driver power input to the motor or controls must be capable of measuring true root mean squared (RMS) current, true RMS voltage, and real power up to the 40th harmonic of fundamental supply source frequency, and have a combined accuracy of ±2.0 percent of the measured value at the fundamental supply source frequency.

3.1.2 Instruments for measuring distance (*e.g.,* height above the reference plane or water level) must be accurate to and have a resolution of at least ±0.1 inch.

3.2 Calibration. Calibration requirements for instrumentation are specified in Appendix D of HI 40.6–2021. Historical calibration data may be used to justify time periods up to three times longer than those specified in Table D.1 of HI 40.6–2021 provided the supporting historical data shows maintenance of calibration of the given instrument up to the selected extended calibration interval on at least two unique occasions, based on the interval specified in HI 40.6–2021.

4.0 Test Conditions and Tolerances

4.1 Pump Specifications. Conduct testing at full impeller diameter in accordance with the test conditions, stabilization requirements, and specifications of HI 40.6–2021 section 40.6.3, ''Pump efficiency testing''; section 40.6.4, ''Considerations when determining the efficiency of certain pumps''; section 40.6.5.4 (including appendix A of HI 40.6–2021), ''Test arrangements''; and section 40.6.5.5, ''Test conditions''.

4.2 Power Supply Requirements. The following conditions also apply to the mains power supplied to the DPPP motor or controls, if any:

(a) Maintain the voltage within ±5 percent of the rated value of the motor,

(b) Maintain the frequency within ±1 percent of the rated value of the motor,

(c) Maintain the voltage unbalance of the power supply within ±3 percent of the value with which the motor was rated, and

(c) Maintain total harmonic distortion below 12 percent throughout the test.

4.3 Test Conditions. Testing must be carried out with water that is between 50 and 107 °F with less than or equal to 15 nephelometric turbidity units (NTU).

4.4 Tolerances. For waterfall pumps, multi-speed self-priming and non-self-priming pool filter pumps, and variable-speed self-priming and non-self-priming pool filter pumps all measured load points must be within ±2.5 percent of the specified head value and comply with any specified flow values or thresholds. For all other dedicated-purpose pool pumps, all measured load points must be within the greater of ±2.5 percent of the specified flow rate values or ±0.5 gpm and comply with any specified head values or thresholds.

5.0 Data Collection and Stabilization

5.1 Damping Devices. Use of damping devices, as described in Section 40.6.3.2.2 of HI 40.6–2021, are only permitted to integrate up to the data collection interval used during testing.

5.2 Stabilization. Record data at any tested load point only under stabilized conditions, as defined in HI 40.6–2021 section 40.6.5.5.1, where a minimum of two measurements are used to determine stabilization.

5.3 Test Points. Measure the flow rate in gpm, pump total head in ft, the driver power input in W, and the speed of rotation in rpm at each load point specified in table 1 of this appendix for each DPPP variety and speed configuration:

TABLE 1—LOAD POINTS (i) AND WEIGHTS (w_i) FOR EACH DPPP VARIETY AND SPEED CONFIGURATION

DPPP varieties	Speed configuration(s)	Number of load points (n)	Load point (i)	Test points		
				Flow rate (Q) (GPM)	Head (H) (ft)	Speed (rpm)
Self-Priming Pool Filter Pumps And Non-Self-Priming Pool Filter Pumps.	Single-speed dedicated-purpose pool pumps and all self-priming and non-self-priming pool filter pumps not meeting the definition of two-*, multi-, or variable-speed dedicated-purpose pool pump.	1	High	Q_{high} (gpm) = $Q_{max\_\_speed@C}$ **.	$H = 0.0082 \times Q_{high}^2$.	Maximum speed.
	Two-speed dedicated-purpose pool pumps *.	2	Low	Q_{low} (gpm) = Flow rate associated with specified head and speed that is not below: • 31.1 gpm if rated hydraulic horsepower is >0.75 or. • 24.7 gpm if rated hydraulic horsepower is ≤0.75.	$H = 0.0082 \times Q_{low}^2$.	Lowest speed capable of meeting the specified flow and head values, if any.***
			High	Q_{high} (gpm) = $Q_{max\_\_speed@C}$ **.	$H = 0.0082 \times Q_{low}^2$.	Maximum speed.
	Multi-speed and variable-speed dedicated-purpose pool pumps.	2	Low	Q_{low} (gpm) = • If rated hydraulic horsepower is >0.75, then $Q_{low} \geq 31.1$ gpm. • If rated hydraulic horsepower is ≤0.75, then $Q_{low} \geq 24.7$ gpm.	$H = 0.0082 \times Q_{low}^2$.	Lowest speed capable of meeting the specified flow and head values.
			High	Q_{high} (gpm) $\geq 0.8 \times Q_{max\_\_speed@C}$ **.	$H = 0.0082 \times Q_{high}^2$.	Lowest speed capable of meeting the specified flow and head values.
Waterfall Pumps	Single-speed dedicated-purpose pool pumps.	1	High	Q_{low} (gpm) = Flow corresponding to specified head.	17.0 ft	Maximum speed.
Pressure Cleaner Booster Pumps.	Any	1	High	10.0 gpm	≥60.0 ft	Lowest speed capable of meeting the specified flow and head values.

* In order to apply the test points for two-speed self-priming and non-self-priming pool filter pumps, self-priming pool filter pumps that are greater than or equal to 0.711 rated hydraulic horsepower that are two-speed dedicated-purpose pool pumps must also be distributed in commerce either:

(a) With a pool pump control (variable speed drive and user interface or switch) that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times or

(b) Without a pool pump control that has such capability, but without which the pump is unable to operate. Two-speed self-priming pool filter pumps greater than or equal to 0.711 rated hydraulic horsepower that do not meet these requirements must be tested using the load point for single-speed self-priming or non-self-priming pool filter pumps, as appropriate.

** $Q_{max\_\_speed@C}$ = Flow at max speed on curve C (gpm).

*** If a two-speed pump has a low speed that results in a flow rate below the specified values, the low speed of that pump shall not be tested.

6.0 Calculations

6.1 Determination of Weighted Energy Factor. Determine the WEF as a ratio of the measured flow and driver power input to the dedicated-purpose pool pump in accordance with the following equation:

$$WEF = \frac{\sum_{i=1}^{n}\left(w_i \times \frac{Q_i}{1000} \times 60\right)}{\sum_{i=1}^{n}\left(w_i \times \frac{P_i}{1000}\right)}$$

Where:

WEF = Weighted Energy Factor in kgal/kWh;

W_i = weighting factor at each load point *i,* as specified in section 6.2 of this appendix;

Q_i = flow at each load point *i,* in gpm;

P_i = driver power input to the motor (or controls, if present) at each load point *i,* in watts;

i = load point(s), defined uniquely for each DPPP variety and speed configuration as specified in section 5.3 of this appendix; and

n = number of load point(s), defined uniquely for each DPPP variety and speed configuration as specified in section 5.3 of this appendix.

6.2 Weights. When determining WEF, apply the weights specified in table 2 of this appendix for the applicable load points, DPPP varieties, and speed configurations:

TABLE 2—LOAD POINT WEIGHTS (w_i)

DPPP varieties	Speed configuration(s)	Load point(s) *i*	
		Low flow	High flow
Self-Priming Pool Filter Pumps and Non-Self-Priming Pool Filter Pumps.	Single-speed dedicated-purpose pool pumps and all self-priming and non-self-priming pool filter pumps not meeting the definition of two-*, multi-, or variable-speed dedicated-purpose pool pump.	.....	1.0
	Two-speed dedicated-purpose pool pumps *	0.80	0.20
	Multi-speed and variable-speed dedicated-purpose pool pumps	0.80	0.20
Waterfall Pumps	Single-speed dedicated-purpose pool pumps	.....	1.0
Pressure Cleaner Booster Pump	Any	.....	1.0

* In order to apply the test points for two-speed self-priming and non-self-priming pool filter pumps, self-priming pool filter pumps that are greater than or equal to 0.711 rated hydraulic horsepower that are two-speed dedicated-purpose pool pumps must also be distributed in commerce either:

(a) With a pool pump control (variable speed drive and user interface or switch) that changes the speed in response to pre-programmed user preferences and allows the user to select the duration of each speed and/or the on/off times or

(b) Without a pool pump control that has such capability, but without which the pump is unable to operate. Two-speed self-priming pool filter pumps greater than or equal to 0.711 rated hydraulic horsepower that do not meet these requirements must be tested using the load point for single-speed self-priming or non-self-priming pool filter pumps, as appropriate.

6.3 Determination of Horsepower and True Power Factor Metrics

6.3.1 Determine the pump power output at any load point i using the following equation:

$$P_{u,i} = \frac{Q_i \times H_i \times SG}{3960}$$

Where:

$P_{u,i}$ = the measured pump power output at load point *i* of the tested pump, in hp;

Q_i = the measured flow rate at load point *i* of the tested pump, in gpm;

H_i = pump total head at load point *i* of the tested pump, in ft; and

SG = the specific gravity of water at specified test conditions, which is equivalent to 1.00.

6.3.1.1 Determine the rated hydraulic horsepower as the pump power output measured on the reference curve at maximum rotating speed and full impeller diameter for the rated pump.

6.3.2 For dedicated-purpose pool pumps with single-phase AC motors or DC motors, determine the dedicated-purpose pool pump nominal motor horsepower as the product of the measured full load speed and torque, adjusted to the appropriate units, as shown in the following equation:

$$P_{nm} = \frac{(T \times n)}{5252}$$

Where:

P_{nm} = the dedicated-purpose pool pump nominal total horsepower at full load, in hp;

T = output torque at full load, in lb-ft; and

n = the motor speed at full load, in rpm.

Full-load speed and torque shall be determined based on the maximum continuous duty motor power output rating allowable for the motor's nameplate ambient rating and insulation class.

6.3.2.1 For single-phase AC motors, determine the measured speed and torque at full load according to either section 6.3.2.1.1 or 6.3.2.1.2 of this appendix.

6.3.2.1.1 Use IEEE 114–2010, according to section 1.3 of this appendix, or

6.3.2.1.2 Use the applicable procedures of CSA C747–09 (R2019), according to section 1.1 of this appendix; except in section 6.4(b) the conversion factor shall be 5252, only measurements at full load are required in section 6.5, and section 6.6 shall be disregarded.

6.3.2.2 For DC motors, determine the measured speed and torque at full load according to either section 6.3.2.2.1 or 6.3.2.2.2 of this appendix.

6.3.2.2.1 Use the procedures of IEEE 113–1985, according to section 1.4 of this appendix, or

6.3.2.2.2 Use the applicable procedures of CSA C747–09 (R2019), according to section 1.1 of this appendix; except in section 6.4(b) the conversion factor shall be 5252, only measurements at full load are required in section 6.5, and section 6.6 shall be disregarded (incorporated by reference, see § 431.463).

6.3.3 For dedicated-purpose pool pumps with single-phase AC motors or DC motors, the dedicated-purpose pool pump service factor is equal to 1.0.

6.3.4 Determine the dedicated-purpose pool pump motor total horsepower according to section 6.3.4.1 of this appendix for dedicated-purpose pool pumps with single-phase AC motors or DC motors and section 6.3.4.2 of this appendix for dedicated-purpose pool pumps with polyphase AC motors.

6.3.4.1 For dedicated-purpose pool pumps with single-phase AC motors or DC motors, determine the dedicated-purpose pool pump motor total horsepower as the product of the dedicated-purpose pool pump nominal motor horsepower, determined in accordance with section 6.3.2 of this appendix, and the dedicated-purpose pool pump service factor, determined in accordance with section 6.3.3 of this appendix.

6.3.4.2 For dedicated-purpose pool pumps with polyphase AC induction motors, determine the dedicated-purpose pool pump motor total horsepower as the product of the rated nominal motor horsepower and the rated service factor of the motor.

6.3.5 Determine the true power factor at each applicable load point specified in Table 1 of this appendix for each DPPP variety and speed configuration as a ratio of driver power input to the motor (or controls, if present) (P_i), in watts, divided by the product of the voltage in volts and the current in amps at each load point *i,* as shown in the following equation:

$$PF_i = \frac{P_i}{V_i \times I_i}$$

Where:

PF_i = true power factor at each load point *i,* dimensionless;

P_i = driver power input to the motor (or controls, if present) at each load point *i,* in watts;

V_i = voltage at each load point *i,* in volts;

I_i = current at each load point *i,* in amps; and

i = load point(s), defined uniquely for each DPPP variety and speed configuration as specified in section 5.3 of this appendix.

6.4 Determination of Maximum Head. Determine the maximum head for self-priming pool filter pumps, non-self-priming pool filter pumps, and waterfall pumps by measuring the head at maximum speed and the minimum flow rate at which the pump is designed to operate continuously or safely, where the minimum flow rate is assumed to be zero unless stated otherwise in the manufacturer literature.

7.0 Determination of Self-Priming Capability

7.1 Test Method. Determine the vertical lift and true priming time of non-self-priming pool filter pumps and self-priming pool filter pumps that are not already certified as self-priming under NSF/ANSI/CAN 50–2020 by testing such pumps pursuant to section N.3–3 of appendix Normative Annex 3 of NSF/ANSI/CAN 50–2020, except for the modifications and exceptions listed in the following sections 7.1.1 through 7.1.5 of this appendix:

7.1.1 Where section N–3.3.2, ''Apparatus,'' and section N–3.3.4, ''Self-priming capability test method,'' of NSF/ANSI/CAN 50–2020 state that the ''suction line must be essentially as shown in Normative Annex 3, figure 3;'' the phrase ''essentially as shown in Normative Annex 3, figure 3'' means:

(a) The centerline of the pump impeller shaft is situated a vertical distance equivalent to the specified vertical lift (VL), calculated in accordance with section 7.1.1.1. of this appendix, above the water level of a water tank of sufficient volume as to maintain a constant water surface level for the duration of the test;

(b) The pump draws water from the water tank with a riser pipe that extends below the water level a distance of at least 3 times the riser pipe diameter (*i.e.,* 3 pipe diameters);

(c) The suction inlet of the pump is at least 5 pipe diameters from any obstructions, 90° bends, valves, or fittings; and

(d) The riser pipe is of the same pipe diameter as the pump suction inlet.

7. 1.1.1 The vertical lift (VL) must be normalized to 5.0 feet at an atmospheric pressure of 14.7 psia and a water density of 62.4 lb/ft^3 in accordance with the following equation:

$$VL = 5.0ft \times \left(\frac{62.4\,{}^{lb}/_{ft^3}}{\rho_{test}}\right) \times \left(\frac{P_{abs,test}}{14.7psia}\right)$$

Where:

VL = vertical lift of the test apparatus from the waterline to the centerline of the pump impeller shaft, in ft;

ρ_{test} = density of test fluid, in lb/ft^3; and

$P_{abs,test}$ = absolute barometric pressure of test apparatus location at centerline of pump impeller shaft, in psia.

7.1.2 The equipment accuracy requirements specified in section 3, ''Measurement Equipment,'' of this appendix also apply to this section 7, as applicable.

7.1.2.1 All measurements of head (gauge pressure), flow, and water temperature must be taken at the pump suction inlet and all head measurements must be normalized back to the centerline of the pump impeller shaft in accordance with section A.3.1.3.1 of HI 40.6–2021.

7.1.3 All tests must be conducted with clear water that meets the requirements adopted in section 4.3 of this appendix.

7.1.4 In section N–3.3.4, ''Self-priming capability test method,'' of NSF/ANSI/CAN 50–2020, ''the elapsed time to steady discharge gauge reading or full discharge flow'' is determined when the changes in head and flow, respectively, are within the tolerance values specified in table 40.6.3.2.2, ''Permissible amplitude of fluctuation as a percentage of mean value of quantity being measured at any test point,'' of HI 40.6–2021. The measured priming time (MPT) is determined as the point in time when the stabilized load point is first achieved, not when stabilization is determined. In addition, the true priming time (TPT) is equivalent to the MPT.

7.1.5 The maximum true priming time for each test run must not exceed 10.0 minutes. Disregard section N–3.3.5 of NSF/ANSI/CAN 50–2020.

8. Optional Testing and Calculations

8.1 Replacement Dedicated-Purpose Pool Pump Motors. To determine the WEF for replacement DPPP motors, test each replacement DPPP motor paired with each dedicated-purpose pool pump bare pump for which the replacement DPPP motor is advertised to be paired, as stated in the manufacturer's literature for that replacement DPPP motor model, according to the testing and calculations described in sections 2, 3, 4, 5, and 6 of this appendix. Alternatively, each replacement DPPP motor may be tested with the most consumptive dedicated-purpose pool pump bare pump for which it

is advertised to be paired, as stated in the manufacturer's literature for that replacement DPPP motor model. If a replacement DPPP motor is not advertised to be paired with any specific dedicated-purpose pool pump bare pumps, test with the most consumptive dedicated-purpose pool pump bare pump available.

Appendix D to Subpart Y of Part 431 [Redesignated as Appendix C]

■ 11. Appendix D to Subpart Y of Part 431 is redesignated as Appendix C to Subpart Y of Part 431 and amended by:
■ a. In the introductory note, removing the words, ''Note 1 to appendix D'' and adding, in their place, the words ''Note 1 to appendix C''; and
■ b. In section 2.1, in the heading of Table 1, removing the words, ''Table 1 to Appendix D to Subpart Y of Part 431'' and adding, in their place, the words ''Table 1 to Appendix C to Subpart Y of Part 431.''

[FR Doc. 2022–24201 Filed 12–1–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1444; Airspace Docket No. 22–AWP–74]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Williams, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Williams, AZ. The FAA is proposing this action to support the establishment of new public instrument procedures.

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1444/Airspace Docket No. 22–AWP–74 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward form 700 feet above the surface at H.A. Clark Memorial Field, Williams, AZ, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1444/Airspace Docket No. 22–AWP–74.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 20-mile radius of H.A. Clark Memorial Field, Williams, AZ.

This action supports the establishment of public instrument procedures at H.A. Clark Memorial Field.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022,

which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP AZ E5 Williams, AZ [Establish]

H.A. Clark Memorial Field, AZ
(Lat. 35°18′20″ N, long. 112°11′40″ W)

That airspace extending upward from 700 feet above the surface within a 20-mile radius of H.A. Clark Memorial Field.

Issued in Fort Worth, Texas, on November 28, 2022.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26141 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1465; Airspace Docket No. 22–AGL–35]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Minocqua-Woodruff, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Minocqua-Woodruff, WI. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Woodruff localizer (LOC). The name of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1465/Airspace Docket No. 22–AGL–35 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Lakeland Airport/Noble F. Lee Memorial Field, Minocqua-Woodruff, WI, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1465/Airspace Docket No. 22–AGL–35.'' The postcard

will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Lakeland Airport/Noble F. Lee Memorial Field, Minocqua-Woodruff, WI, by adding an extension 4 miles each side of the 001° bearing from the airport extending from the 6.6-mile radius to 11.5 miles north of the airport; removing the city associated with the airport from the airspace legal description to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters; and updating the name of the airport (previously Lakeland/Nobel F. Lee Memorial Field Airport) to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Woodruff LOC which provided navigation information for the instrument procedures at this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL WI E5 Minocqua-Woodruff, WI [Amended]

Lakeland Airport/Noble F. Lee Memorial Field, WI
(Lat. 45°55′41″ N, long. 89°43′51″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Lakeland Airport/Noble F. Lee Memorial Field Airport; and within 4 miles each side of the 001° bearing from the airport extending from the 6.6-mile radius to 11.5 miles north of the airport.

Issued in Fort Worth, Texas, on November 28, 2022.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26146 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1464; Airspace Docket No. 22–AGL–34]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Austin, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Austin, MN. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Austin very high frequency (VHF) omnidirectional range (VOR)/distance measuring equipment (DME). The

geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1464/Airspace Docket No. 22–AGL–34 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Austin Municipal Airport, Austin, MN, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1464/Airspace Docket No. 22–AGL–34.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within a 7.3-mile (increased from a 6.3-mile) radius of Austin Municipal Airport, Austin, MN; removing the Austin VOR/DME and the associated extension from the airspace legal description; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Austin VOR/DME which provided navigation information for the instrument procedures at this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F,

''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MN E5 Austin, MN [Amended]

Austin Municipal Airport, MN
(Lat. 43°39′46″ N, long. 92°55′59″ W)

That airspace extending upward from 700 feet above the surface within a 7.3-mile radius of the Austin Municipal Airport.

Issued in Fort Worth, Texas, on November 28, 2022.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26145 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1442; Airspace Docket No. 22–ASW–23]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; San Saba, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at San Saba, TX. The FAA is proposing this action to support the establishment of public instrument procedures at San Saba County Municipal Airport, San Saba, TX.

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1442/Airspace Docket No. 22–ASW–23 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward form 700 feet above the surface at San Saba County Municipal Airport, San Saba, TX, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1442/Airspace Docket No. 22–ASW–23.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace

Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of San Saba County Municipal Airport, San Saba, TX.

This action supports the establishment of public instrument procedures at San Saba County Municipal Airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 San Saba, TX [Establish]

San Saba County Municipal Airport, TX
(Lat. 31°14′09″ N, long. 98°43′04″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of San Saba County Municipal Airport.

Issued in Fort Worth, Texas, on November 28, 2022.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26180 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1466; Airspace Docket No. 22–AGL–36]

RIN 2120–AA66

Proposed Amendment of Class D and E Airspace and Revocation of Class E Airspace; Alton/St. Louis, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D and Class E airspace and revoke Class E airspace at Alton/St. Louis, IL. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Civic Memorial non-directional beacon (NDB).

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1466/Airspace Docket No. 22–AGL–36 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class D airspace and Class E airspace extending upward from 700 feet above the surface and revoke the Class E airspace designated as an extension of Class D airspace at St. Louis Regional Airport, Alton/St. Louis,

IL, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1466/Airspace Docket No. 22–AGL–36.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Amending the Class D airspace at St. Louis Regional Airport, Alton/St. Louis, IL, by replacing the outdated term ''Notice to Airmen'' with ''Notice to Air Missions':

Removing the Class E airspace designated as an extension to Class D airspace at St. Louis Regional Airport as it is no longer required;

And amending the Class E airspace extending upward from 700 feet above the surface at St. Louis Regional Airport by removing the Civic Memorial NDB and associated extension from the airspace legal description.

This action is due to an airspace review conducted as part of the decommissioning of the Civic Memorial NDB which provided navigation information for the instrument procedures at this airport.

Class D and E airspace designations are published in paragraphs 5000, 6004, and 6005, respectively, of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL IL D Alton/St. Louis, IL [Amended]

St. Louis Regional Airport, IL
(Lat. 38°53′24″ N, long. 90°02′46″ W)

That airspace extending upward from the surface to and including 3,000 feet MSL within a 4.4-mile radius of the St. Louis Regional Airport, excluding that airspace within the St. Louis, MO, Class B airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AGL IL E4 Alton/St. Louis, IL [Remove]

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL IL E5 Alton/St. Louis, IL [Amended]

St. Louis Regional Airport, IL
(Lat. 38°53′24″ N, long. 90°02′46″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of St. Louis Regional Airport.

Issued in Fort Worth, Texas, on November 29, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26247 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1443; Airspace Docket No. 22–ASW–24]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Smithville, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Smithville, TX. The FAA is proposing this action to support the establishment of public instrument procedures at Smithville Crawford Municipal Airport, Smithville, TX.

DATES: Comments must be received on or before January 17, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–1443/Airspace Docket No. 22–ASW–24 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward form 700 feet above the surface at Smithville Crawford Municipal Airport, Smithville, TX, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–1443/Airspace Docket No. 22–ASW–24.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 7.4-mile radius of Smithville Crawford Municipal Airport, Smithville, TX.

This action supports the establishment of public instrument procedures at Smithville Crawford Municipal Airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Smithville, TX [Establish]

Smithville Crawford Municipal Airport, TX (Lat. 30°01′42″ N, long. 97°10′01″ W)

That airspace extending upward from 700 feet above the surface within a 7.4-mile radius of Smithville Crawford Municipal Airport.

Issued in Fort Worth, Texas, on November 28, 2022.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–26181 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

[File No. R307000]

Petition for Rulemaking of the Center for Digital Democracy, Fairplay, et al.

AGENCY: Federal Trade Commission.

ACTION: Receipt of petition; request for comment.

SUMMARY: Please take notice that the Federal Trade Commission (''Commission'') received a petition for rulemaking from the Center for Digital Democracy, Fairplay, Accountable Tech, American Academy of Pediatrics, Becca Schmill Foundation, Inc., Berkeley Media Studies Group, C. Everett Koop Institute at Dartmouth, Center for Humane Technology, Children and Screens: Institute of Digital Media and Child Development, Eating Disorders Coalition, Electronic Privacy Information Center (EPIC), LookUp.live, Lynn's Warriors, Network for Public Education, Parent Coalition for Student Privacy, ParentsTogether, Protect Young Eyes, Public Citizen, Together for Girls, UConn Rudd Center for Food Policy and Health, and U.S. Public Interest Research Group (collectively, ''Petitioners''), and has published that petition online at *https://www.regulations.gov.* This petition asks the Commission to promulgate a rule prohibiting the use of certain types of engagement-optimizing design practices on individuals under the age of 18 (''minors'') in connection with internet services. The Commission invites written comments concerning the petition. Publication of this petition is pursuant to the Commission's Rules of Practice and Procedure and does not affect the legal status of the petition or its final disposition.

DATES: Comments must identify the petition docket number and be filed by January 3, 2023.

ADDRESSES: You may view the petition, identified by docket number FTC–2022–0073, and submit written comments concerning its merits by using the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit sensitive or confidential information. You may read background documents or comments received at *https://www.regulations.gov* at any time.

FOR FURTHER INFORMATION CONTACT: Daniel Freer (phone: 202–326–2663, email: *dfreer@ftc.gov*), Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(1)(B), and FTC Rule 1.31(f), 16 CFR 1.31(f), notice is hereby given that the above-captioned petition has been filed with the Secretary of the Commission and has been placed on the public record for a period of 30 days. Any person may submit comments in support of or in opposition to the petition. All timely and responsive comments submitted in connection with this petition will become part of the public record.

The Commission will not consider the petition's merits until after the comment period closes. It may grant or deny the petition in whole or in part, and it may deem the petition insufficient to warrant commencement of a rulemaking proceeding. The purpose of this document is to facilitate public comment on the petition to aid the Commission in determining what, if any, action to take regarding the request contained in the petition. This document is not intended to start, stop, cancel, or otherwise affect rulemaking proceedings in any way.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical

records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2).

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 601 note.

April J. Tabor,

Secretary.

[FR Doc. 2022–26254 Filed 12–1–22; 8:45 am]

BILLING CODE 6750–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Chapter II

[Release Nos. 33–11136; 34–96386; IC–34765; File No. S7–27–22]

List of Rules To Be Reviewed Pursuant to the Regulatory Flexibility Act

AGENCY: Securities and Exchange Commission.

ACTION: Publication of list of rules scheduled for review.

SUMMARY: The Securities and Exchange Commission is publishing a list of rules to be reviewed pursuant to Section 610 of the Regulatory Flexibility Act. The list is published to provide the public with notice that these rules are scheduled for review by the agency and to invite public comment on whether the rules should be continued without change, or should be amended or rescinded to minimize any significant economic impact of the rules upon a substantial number of small entities.

DATES: Comments should be submitted by January 3, 2023.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/submitcomments.html*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–27–22 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–27–22. 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 of submission. The Commission will post all comments on the Commission's website (*http://www.sec.gov/rules/other.shtml*). Comments are also 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. Operating conditions may limit access to the Commission's Public Reference Room. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Sandra Sojka, General Attorney, Office of the General Counsel, 202–551–4928.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act (''RFA''), codified at 5 U.S.C. 601–612, requires an agency to review its rules that have a significant economic impact upon a substantial number of small entities within ten years of the publication of such rules as final rules. 5 U.S.C. 610(a). The purpose of the review is ''to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of such small entities.'' 5 U.S.C. 610(a). The RFA sets forth specific considerations that must be addressed in the review of each rule:

- the continued need for the rule;
- the nature of complaints or comments received concerning the rule from the public;
- the complexity of the rule;
- the extent to which the rule overlaps, duplicates or conflicts with other federal rules, and, to the extent feasible, with state and local governmental rules; and
- the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. 5 U.S.C. 610(b).

The list below includes rules adopted in 2013 that may have a significant economic impact on a substantial number of small entities (but excludes rules that have been substantially changed since adoption, rules that are minor amendments to previously adopted rules, and rules that are ministerial, procedural, or technical in nature). Where the Commission has previously made a determination of a rule's impact on small businesses, the determination is noted on the list.

The Commission particularly solicits public comment on whether the rules listed below affect small businesses in new or different ways than when they were first adopted. The rules and forms listed below are scheduled for review by staff of the Commission.

Title: Removal of Certain References to Credit Ratings Under the Investment Company Act.

Citation: 17 CFR 239, 17 CFR 270.5b-3, and 17 CFR 274.

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78c(b), 78*l,* 78m, 78n, 78*o*(d), 78*o*–7, 78*o*–7 note, 78u–5, 78w(a), 78*ll,* 78mm, 80a–1 *et seq.,* 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, 80a– 34(d), 80a–37, 80a–39; and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010).

Description: The Commission adopted amendments to a rule and three forms under the Investment Company Act of 1940 (''Investment Company Act'') and the Securities Act of 1933 (''Securities Act'') in order to implement a provision of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). Specifically, rule 5b–3 under the Investment Company Act contained a reference to credit ratings in determining when an investment company (''fund'') may treat a repurchase agreement as an acquisition of securities collateralizing the repurchase agreement for certain purposes under the Investment Company Act. The amendments replaced this reference to credit ratings with an alternative standard designed to retain a similar degree of credit quality to that in prior rule 5b–3. The Commission also adopted amendments to Forms N–1A, N–2, and N–3 under the Investment Company Act and the Securities Act to eliminate the required use of NRSRO credit ratings when a fund chooses to depict its portfolio holdings by credit quality.

Prior RFA Analysis: When the Commission adopted the amendments on December 27, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 33–9506, available at: *https://www.federalregister.gov/documents/2014/01/08/2013-31425/removal-of-certain-references-to-credit-ratings-under-the-investment-company-act.* The Commission received no comments on its Initial Regulatory Flexibility Analysis published in the proposing release, Release No. 33–9193 (March 3, 2011), available at: *https://www.federalregister.gov/documents/*

2011/03/09/2011-5184/references-to-credit-ratings-in-certain-investment-company-act-rules-and-forms.

* * * * *

Title: Registration of Municipal Advisors.

Citation: 17 CFR 200.19c, 17 CFR 200.19d, 17 CFR 200.30–3a, 17 CFR 200.30–18; 17 CFR 240.15Ba1–1, 17 CFR 240.15Ba1–2, 17 CFR 240.15Ba1–3, 17 CFR 240.15Ba1–4, 17 CFR 40.15Ba1–5, 17 CFR 240.15Ba1–6, 17 CFR 240.15Ba1–7, 17 CFR 240.15Ba1–8, 17 CFR 240.15Bc4–1; 17 CFR 249.1300, 17 CFR 249.1300T, 17 CFR 249.1310, 17 CFR 249.1320, 17 CFR 249.1330, and 17 CFR 249.1300T.

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77*o,* 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78a *et seq.,* 78c, 78d, 78d–1, 78d–2, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78*ll*(d), 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.,* 7202, 7211 *et seq.,* 12 U.S.C. 5221(e)(3), 12 U.S.C. 5461 *et seq.,* and 18 U.S.C. 1350, unless as otherwise noted.

Description: The Commission adopted new Rules 15Ba1–1 through 15Ba1–8, new Rule 15Bc4–1, and new Forms MA, MA–I, MA–W, and MA–NR under the Securities Exchange Act of 1934 (''Exchange Act'') to implement provisions of Title IX of the Dodd-Frank Act that required the Commission to establish a registration regime for municipal advisors and impose certain record-keeping requirements on such advisors. The rules and forms are designed to give effect to provisions of Title IX of the Dodd-Frank Act that, among other things, required the Commission to establish a registration regime for municipal advisors and impose certain record-keeping requirements on such advisors.

Prior RFA Analysis: When the Commission adopted the rules and forms on September 20, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 34–70462, available at: *https://www.federalregister.gov/documents/2013/11/12/2013-23524/registration-of-municipal-advisors.* The Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing release, Release No. 34–63576 (Dec. 20, 2010), available at: *https://www.federalregister.gov/documents/2011/01/06/2010-32445/registration-of-municipal-advisors,* and considered comments received at that time.

* * * * *

Title: Broker Dealer Reports.

Citation: 17 CFR 240.17a–5, 17 CFR 240.17a–11, and 17 CFR 249.639.

Authority: 15 U.S.C. 78a *et seq.,* 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78a *et seq.,* 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b– 4, 80b–11, 7201 *et seq.,* 8302, 7 U.S.C. 2(c)(2)(E), 12 U.S.C. 5221(e)(3), 12 U.S.C. 5461 *et seq.,* 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat. 1376, (2010).

Description: The Commission amended certain broker-dealer annual reporting, audit, and notification requirements under the Exchange Act. The amendments included a requirement that broker-dealer audits be conducted in accordance with standards of the Public Company Accounting Oversight Board (''PCAOB'') in light of explicit oversight authority provided to the PCAOB by the Dodd-Frank Act to oversee these audits. The amendments further required a broker-dealer that clears transactions or carries customer accounts to agree to allow representatives of the Commission or the broker-dealer's designated examining authority (''DEA'') to review the documentation associated with certain reports of the broker-dealer's independent public accountant and to allow the accountant to discuss the findings relating to the reports of the accountant with those representatives when requested in connection with a regulatory examination of the broker-dealer. Finally, the amendments required a broker-dealer to file a new form with its DEA that elicits information about the broker-dealer's practices with respect to the custody of securities and funds of customers and non-customers.

Prior RFA Analysis: When the Commission adopted the amendments and new form on July 30, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 34–70073, available at: *https://www.federalregister.gov/documents/2013/08/21/2013-18738/broker-dealer-reports.* The Commission received no comments on the Initial Regulatory Flexibility Analysis included in the proposing release, Release No. 34–64676 (June 15, 2011), available at: *https://www.federalregister.gov/documents/2011/06/27/2011-15341/broker-dealer-reports.*

* * * * *

Title: Financial Responsibility Rules for Broker-Dealers.

Citation: 17 CFR 240.15c3–1, 17 CFR 240.15c3–1a, 17 CFR 240.15c3–2, 17 CFR 240.15c3–3, 17 CFR 240.15c3–3a, 17 CFR 240.17a–3, 17 CFR 240.17a–4, and 17 CFR 240.17a–11.

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et. seq.,* 8302, 7 U.S.C. 2(c)(2)(E), 12 U.S.C. 5221(e)(3), 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat. 1376, (2010).

Description: The Commission adopted amendments to the net capital (Rule 15c3–1), customer protection (Rule 15c3–3), books and records (Rules 17a–3 and 17a– 4), and notification rules for broker-dealers (Rule 17a–11) promulgated under the Exchange Act. The amendments were designed to address several areas of concern regarding the financial responsibility requirements for broker-dealers. The amendments also updated certain financial responsibility requirements and made certain technical amendments.

Prior RFA Analysis: When the Commission adopted the amendments on July 30, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 34–70072, available at: *https://www.federalregister.gov/documents/2013/08/21/2013-18734/financial-responsibility-rules-for-broker-dealers.* The Commission solicited comment on the Initial Regulatory Flexibility Analysis included in the proposing release, Release No. 34–66910 (May 3, 2012), available at: *https://www.federalregister.gov/documents/2012/05/09/2012-11133/amendments-to-financial-responsibility-rules-for-broker-dealers,* and considered comments received at that time.

* * * * *

Title: Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings.

Citation: 17 CFR 230.144A, 17 CFR 230.500(c), 17 CFR 230.501, 17 CFR 230.502, 17 CFR 230.506, 17 CFR 239.500, 17 CFR 242.101, 17 CFR 242.102, and 17 CFR 242.104.

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77r, 77s, 77q(a), 77s(a), 77z–2, 77z–3, 77sss, 78b, 78c, 78d, 78g(c)(2), 78i(a), 78j, 78k–1(c), 78*l,* 78m, 78n, 78*o,* 78*o*–7 note, 78*o*(b), 78*o*(c), 78*o*(d), 78*o*(g), 78q(a), 78q(b), 78q(h), 78t, 78u–5, 78w, 78w(a), 78dd-1, 78*ll,* 78*ll*(d), 78mm, 80a–2(a), 80a–3, 80a-8, 80a–9, 80a–10,

80a–13, 80a–23, 80a–24, 80a–26, 80a–28, 80a–29, 80–30, 80a–37; and Pub. L. 112–106, sec. 201(a), 126 Stat. 313 (2012).

Description: The Commission adopted amendments to Rule 506 of Regulation D and Rule 144A under the Securities Act to implement Section 201(a) of the Jumpstart Our Business Startups Act. The amendment to Rule 506 permitted an issuer to engage in general solicitation or general advertising in offering and selling securities pursuant to Rule 506, provided that all purchasers of the securities are accredited investors and the issuer takes reasonable steps to verify that such purchasers are accredited investors. The amendment to Rule 506 also included a non-exclusive list of methods that issuers may use to satisfy the verification requirement for purchasers who are natural persons. The amendment to Rule 144A provided that securities may be offered pursuant to Rule 144A to persons other than qualified institutional buyers, provided that the securities are sold only to persons that the seller and any person acting on behalf of the seller reasonably believe are qualified institutional buyers. The Commission also revised Form D to require issuers to indicate whether they are relying on the provision that permits general solicitation or general advertising in a Rule 506 offering.

Prior RFA Analysis: When the Commission adopted the amendments on July 10, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 33–9415, available at: *https://www.federalregister.gov/documents/2013/07/24/2013-16883/eliminating-the-prohibition-against-general-solicitation-and-general-advertising-in-rule-506-and.* The Commission solicited comment on its Initial Regulatory Flexibility Analysis published in the proposing release, Release No. 33–9354 (August 29, 2012), available at: *https://www.federalregister.gov/documents/2012/09/05/2012-21681/eliminating-the-prohibition-against-general-solicitation-and-general-advertising-in-rule-506-and,* and considered comments received at that time.

* * * * *

Title: Disqualification of Felons and Other ''Bad Actors'' from Rule 506 Offerings

Citation: 17 CFR 200.30–1, 17 CFR 230.145, 17 CFR. 147, 17 CFR 152, 17 CFR 155, 17 CFR 230.501, 17 CFR 230.506, and 17 CFR 239.500

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77d note, 77f, 77g, 77h, 77j, 77*o,* 77r, 77s, 77z–2, 77z–3, 77sss, 78c, 78d, 78d–1, 78d–2, 78j, 78*l,* 78m, 78n, 78*o,* 78*o*(d), 78*o*–7 note, 78t, 78u-5, 78w, 78w(a), 78*ll,* 78*ll*(d), 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–28, 80a–29, 80a–30, 80a–37, 80b–11, 7202; and Pub. L. 112–106, 201(a), 126 Stat. 313 (2012).

Description: The Commission adopted amendments to Rules 501 and 506 of Regulation D and to Form D to implement Section 926 of the Dodd-Frank Act. Section 926 required the Commission to adopt rules that disqualify securities offerings involving certain ''felons and other 'bad actors' '' from reliance on Rule 506 of Regulation D. The rules are ''substantially similar'' to Rule 262 under the Securities Act, which contains the disqualification provisions of Regulation A under the Securities Act, and also cover matters enumerated in Section 926 of the Dodd-Frank Act (including certain state regulatory orders and bars).

Prior RFA Analysis: When the Commission adopted the amendments on July 10, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 33–9414, available at: *https://www.federalregister.gov/documents/2013/07/24/2013-16983/disqualification-of-felons-and-other-bad-actors-from-rule-506-offerings.* The Commission received no comments on its Initial Regulatory Flexibility Analysis published in the proposing release, Release No. 33–9211 (May 25, 2011), available at: *https://www.federalregister.gov/documents/2011/06/01/2011-13370/disqualification-of-felons-and-other-bad-actors-from-rule-506-offerings.*

* * * * *

Title: Identity Theft Red Flags Rules.

Citation: 17 CFR 162.30, 17 CFR 162.31, 17 CFR 162.32, 17 CFR 248.201, and 17 CFR 248.202.

Authority: Sec. 1088, Pub. L. 111–203, 124 Stat. 1376 (2010); 15 U.S.C. 78q, 78q–1, 78*o*–4, 78*o*–5, 78w, 78mm, 80a–30, 80a–37, 80b–4, 80b–11, 1681m(e), 1681s(b), 1681s–3 and note, 1681w(a)(1), 6801–6809, and 6825; and Pub. L. 111–203, secs. 1088(a)(8), (a)(10), and sec. 1088(b), 124 Stat. 1376 (2010).

Description: The Commission and the Commodity Futures Trading Commission (''CFTC'') (together, the ''Commissions'') jointly adopted rules and guidelines to require certain regulated entities to establish programs to address risks of identity theft. These rules and guidelines implemented provisions of the Dodd-Frank Act, which amended the Fair Credit Reporting Act and directed the Commissions to adopt rules requiring entities that are subject to the Commissions' respective enforcement authorities to address identity theft. First, the rules required financial institutions and creditors to develop and implement a written identity theft prevention program designed to detect, prevent, and mitigate identity theft in connection with certain existing accounts or the opening of new accounts. The rules included guidelines to assist entities in the formulation and maintenance of programs that would satisfy the requirements of the rules. Second, the rules established special requirements for any credit and debit card issuers that are subject to the Commissions' respective enforcement authorities, to assess the validity of notifications of changes of address under certain circumstances.

Prior RFA Analysis: When the Commissions adopted the new rules on April 10, 2013, the Commission published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 34–69359, available at: *https://www.federalregister.gov/documents/2013/04/19/2013-08830/identity-theft-red-flags-rules.* The Commission received no comments on its Initial Regulatory Flexibility Analysis published in the proposing release, Release No. IC–29969 (Feb.27, 2012), available at: *https://www.federalregister.gov/documents/2012/03/06/2012-5157/identity-theft-red-flags-rules.*

* * * * *

Title: Lost Securityholders and Unresponsive Payees.

Citation: 17 CFR 240.15b1–6 and 17 CFR 240.17Ad–17.

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78*ll,* 78m, 78mm, 78n, 78n–1, 78*o,* 78*o*–4, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 80a–20, 80a– 23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.,* 18 U.S.C. 1350, and 12 U.S.C. 5221(e)(3), unless otherwise noted.

Description: The Commission adopted amendments to Rule 17Ad–17 to implement the requirements of Section 929W of the Dodd-Frank Act. Section 929W added to Section 17A of the Exchange Act subsection (g), ''Due Diligence for the Delivery of Dividends, Interest, and Other Valuable Property Rights,'' which directs the Commission to revise Exchange Act Rule 17Ad–17, ''Transfer Agents' Obligation to Search for Lost Securityholders'' to: extend the requirements of Rule 17Ad–17 to search

for lost securityholders from only recordkeeping transfer agents to brokers and dealers as well; add a requirement that ''paying agents'' notify ''unresponsive payees'' that a paying agent has sent a securityholder a check that has not yet been negotiated; and add certain other provisions. The Commission also adopted conforming amendment to Rule 17Ad–7(i) and new Rule 15b1–6, a technical rule to help ensure that brokers and dealers have notice of their new obligations with respect to lost securityholders and unresponsive payees.

Prior RFA Analysis: When the Commission adopted the rule amendments on January 16, 2013, it published a Final Regulatory Flexibility Analysis in the adopting release, Release No. 34–68668, available at: *https://www.federalregister.gov/documents/2013/01/23/2013-01269/lost-securityholders-and-unresponsive-payees.* The Commission solicited comment on the Initial Regulatory Flexibility Analysis included in the proposing release, Release No. 34–64099 (March 18, 2011), available at: *https://www.federalregister.gov/documents/2011/03/25/2011-6940/rule-17ad-17-transfer-agents-brokers-and-dealers-obligation-to-search-for-lost-securityholders,* and considered comments received at that time.

* * * * *

By the Commission.

Dated: November 28, 2022

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–26133 Filed 12–1–22; 8:45 am]

BILLING CODE 8011–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2022–0857; FRL–10410–01–R8]

Air Plan Conditional Approval; Colorado; Revisions to Regulation Number 7 and RACT Requirements for 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing conditional approval of portions of State Implementation Plan (SIP) revisions to Colorado Air Quality Control Commission (Commission or AQCC) Regulation Number 7 (Reg. 7), which address Colorado's SIP obligation to require reasonably available control technology (RACT) for sources covered by the 2008 miscellaneous metal and plastic parts coatings (miscellaneous metal coatings) control techniques guidelines (CTG) and major source nitrogen oxides (NO_X) for Moderate nonattainment areas under the 2008 ozone National Ambient Air Quality Standard (NAAQS). These revisions address all of the remaining pieces of the May 31, 2017 and May 10, 2019 submittals that we have not previously acted on. The EPA is taking this action pursuant to the Clean Air Act (CAA).

DATES: Written comments must be received on or before January 3, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2022–0857, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.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.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov.* To reduce the risk of COVID–19 transmission, for this action we do not plan to offer hard copy review of the docket. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, telephone number: (303) 312–6563, email address: *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. What action is the EPA proposing to take?

As explained below, the EPA is proposing to conditionally approve into the SIP certain Reg. 7 rules as meeting the 2008 8-hour ozone NAAQS miscellaneous metal coatings CTG [1] and major source NO_X RACT requirements for the Moderate Denver Metro/North Front Range (DMNFR) Area. The rules that are the subject of this action were not acted on in our July 3, 2018,[2] February 24, 2021,[3] November 5, 2021 [4] rulemakings. This proposed conditional approval is based on the State's commitment to make specified further revisions to these rules, and submit them for approval into the SIP, to address deficiencies identified in the State's May 31, 2017 and May 10, 2019 submittals.

Under section 110(k)(4) of the CAA, the EPA may conditionally approve a plan based on a commitment from a state to adopt specific enforceable measures by a date certain no later than one year from the date of approval. The conditionally approved provisions are a part of the SIP and thus are federally enforceable as of the effective date of the final conditional approval. If the EPA conditionally approves the identified Reg. 7 rules, the State must meet its commitment to submit the necessary SIP revisions to the EPA by June 30,

[1] Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings, EPA–453/R–08–003, September 2008, available at *https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1001JAL.txt.*

[2] Final Rule, Approval and Promulgation of State Implementation Plan Revisions; Colorado; Attainment Demonstration for the 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area, and Approval of Related Revisions, 83 FR 31068, 31069–31072.

[3] Final Rule, Approval and Promulgation of Implementation Plans; Colorado; Revisions to Regulation Number 7 and RACT Requirements for 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area, 86 FR 11125, 11126 –11127.

[4] Final Rule, Approval and Promulgation of Implementation Plans; Colorado; Revisions to Regulation Number 7; Aerospace, Oil and Gas, and Other RACT Requirements for the 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area, 86 FR 61071, 61072.

2023. If the State fails to do so, this action will automatically become a disapproval on that date. If the State submits timely SIP revisions but the EPA finds the SIP submittal to be incomplete, this action will become a disapproval on the date of the EPA's incompleteness finding. In either case, the EPA will notify the State by letter that the conditional approval has converted to a disapproval, and as of the date of that notification the conditionally approved measures will no longer be a part of the approved Colorado SIP. The EPA subsequently will publish a document in the **Federal Register** notifying the public that the conditional approval converted to a disapproval.

If the State submits the necessary SIP revisions by June 30, 2023, the conditionally approved provisions will remain a part of the SIP until the EPA approves or disapproves the new SIP revisions through notice-and-comment rulemaking. If the EPA takes final action approving the new revisions into the SIP, in the same final action the EPA will also convert the conditional approval to a full approval by making appropriate revisions to the description of the SIP in the Code of Federal Regulations. If the EPA disapproves the new SIP revisions, the conditional approval will convert to a disapproval, and the conditionally approved provisions will no longer be a part of the approved Colorado SIP.

Any conditional approval action that converts to a disapproval will start an 18-month clock for application of mandatory sanctions under CAA section 179(b) and a two-year clock for the EPA to promulgate a Federal implementation plan under CAA section 110(c)(1). The basis for our proposed action is discussed in this proposed rulemaking. Technical information that we are relying on, as well as the State's October 13, 2022 commitment letter, is in the docket, available at *https://www.regulations.gov,* Docket No. EPA–R08–OAR–2022–0857.

II. Background

2008 8-Hour Ozone NAAQS Nonattainment

On March 12, 2008, the EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 parts per million (ppm) (based on the annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years), to provide increased protection of public health and the environment.[5] The 2008 ozone NAAQS retains the same general form and averaging time as the 0.08 ppm NAAQS set in 1997, but is set at a more protective level. Specifically, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm.[6] Effective July 20, 2012, the EPA designated as nonattainment any area that was violating the 2008 8-hour ozone NAAQS based on the three most recent years (2008–2010) of air monitoring data.[7] With that rulemaking, the DMNFR was designated nonattainment and classified as Marginal.[8] Ozone nonattainment areas are classified based on the severity of their ozone levels, as determined using the area's design value. The design value is the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration at a monitoring site.[9] Areas designated as nonattainment at the Marginal classification level were required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2015, based on 2012–2014 monitoring data.[10]

On May 4, 2016, the EPA published its determination that the Denver Area, among other areas, had failed to attain the 2008 8-hour ozone NAAQS by the attainment deadline, and that it was accordingly reclassified to Moderate ozone nonattainment status.[11] Colorado submitted SIP revisions to the EPA on May 31, 2017 to meet the Denver Area's requirements under the Moderate classification.[12] The EPA took final action on July 3, 2018, approving the majority of the May 31, 2017 submittal, but deferring action on portions of the submitted Reg. 7 RACT rules.[13] On February 24, 2021, the EPA took final action approving additional measures as addressing Colorado's RACT SIP obligations for Moderate ozone nonattainment areas.[14] Areas that were designated as Moderate nonattainment were required to attain the 2008 8-hour ozone NAAQS no later than July 20, 2018, based on 2015–2017 monitoring data.[15] On December 26, 2019, the EPA published its determination that the Denver Area, among other areas, had failed to attain the 2008 8-hour ozone NAAQS by the attainment deadline, and that it was accordingly reclassified to Serious ozone nonattainment status.[16]

III. Summary of the State's SIP Submittals

We are proposing to take action on Colorado SIP submittals made on two different dates:

May 31, 2017 Submittal

This submittal contains the State's Moderate ozone attainment plan for the 2008 8-hour ozone NAAQS, including RACT requirements for 100 tons per year (tpy) major sources of VOC and/or NO_X and for sources subject to a CTG.

We have previously acted on all parts of this SIP submittal except for the State's determination for the miscellaneous metal coatings CTG and major source NO_X RACT, as to which we are now proposing conditional approval.

May 10, 2019 Submittal

This submittal contains amendments to Reg. 7 that establish categorical RACT requirements for major sources of NO_X in the DMNFR Area that emit 100 tpy or more. Specifically, on July 19, 2018 the AQCC adopted RACT requirements for boilers, stationary combustion turbines, lightweight aggregate kilns, glass melting furnaces, and compression ignition reciprocating internal combustion engines (collectively referred to as ''stationary combustion equipment'') located at major sources of NO_X.[17] We have previously acted on all parts of this SIP submittal except for revisions to Reg. 7, Part E, Section II.A.4.d., concerning glass melting

[5] Final rule, National Ambient Air Quality Standards for Ozone, 73 FR 16436 (March 27, 2008). The EPA has since further strengthened the ozone NAAQS, but the 2008 8-hour standard remains in effect. See Final Rule, National Ambient Air Quality Standards for Ozone, 80 FR 65292 (Oct. 26, 2015).

[6] 40 CFR 50.15(b).

[7] Final rule, Air Quality Designations for the 2008 Ozone National Ambient Air Quality Standards, 77 FR 30088 (May 21, 2012).

[8] *Id.* at 30110. The nonattainment area includes Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson Counties, and portions of Larimer and Weld Counties. *See* 40 CFR 81.306.

[9] 40 CFR part 50, appendix I.

[10] *See* 40 CFR 51.903.

[11] Final rule, Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas for the 2008 Ozone National Ambient Air Quality Standards, 81 FR 26697 (May 4, 2016).

[12] CAA section 182, 42 U.S.C. 7511a, outlines SIP requirements applicable to ozone nonattainment areas in each classification category. Areas classified Moderate under the 2008 8-hour ozone NAAQS had a submission deadline of January 1, 2017 for these SIP revisions (81 FR at 26699).

[13] 83 FR 31068.

[14] 86 FR 11125.

[15] *See* 40 CFR 51.903.

[16] Final rule, Finding of Failure To Attain and Reclassification of Denver Area for the 2008 Ozone National Ambient Air Quality Standard, 84 FR 70897 (Dec. 26, 2019); *see* 40 CFR 81.306.

[17] On June 29, 2018, the EPA provided comments on Colorado's revised draft ozone SIPs for the DMNFR Area, including the TSD and rules in Reg.7, Section XVI.D.4. These written comments from the EPA included some comments applicable to the rules we are proposing to act on in this document. The comment letters can be found within the docket for this action on *www.regulations.gov.*

furnaces, as to which we are now proposing conditional approval.

IV. Procedural Requirements

The CAA requires that states meet certain procedural requirements before submitting SIP revisions to the EPA, including the requirement that states adopt SIP revisions after reasonable notice and public hearing.[18] For the May 31, 2017 submittal, the AQCC provided notice in the Colorado Register on August 10, 2016,[19] and held a public hearing on the SIP revisions on November 17, 2016. The Commission adopted the SIP revisions on November 17, 2016. The SIP revisions became state-effective on January 14, 2017.

For the May 10, 2019 submittal, the AQCC provided notice in the Colorado Register on May 10, 2018,[20] and held a public hearing on the revisions on July 19, 2018. The Commission adopted the SIP revisions on July 19, 2018. The SIP revisions became state-effective on September 14, 2018.

Accordingly, we propose to find that Colorado met the CAA's procedural requirements for reasonable notice and public hearing.

V. Reasonably Available Control Technology (RACT) Analysis

A. Background

Section 172(c)(1) of the CAA requires that SIPs for nonattainment areas ''provide for the implementation of all reasonably available control measures as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology).'' The EPA has defined RACT as ''[t]he lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.'' [21] The EPA provides guidance concerning what types of controls may constitute RACT for a given source category by issuing CTG and Alternative Control Techniques (ACT) documents.[22] States must submit a SIP revision requiring the implementation of RACT for each source category in the area for which the EPA has issued a CTG, and for any major source in the area not covered by a CTG.[23]

For a Moderate, Serious, or Severe area a major stationary source is one that emits, or has the potential to emit, 100, 50, or 25 tpy or more, respectively, of VOCs or NO_X.[24] Accordingly, for the DMNFR Serious nonattainment area, a major stationary source is one that emits, or has the potential to emit, 50 tpy or more of VOCs or NO_X. RACT can be adopted in the form of emission limitations or ''work practice standards or other operation and maintenance requirements,'' as appropriate.[25]

As part of its May 31, 2017 Moderate ozone attainment plan, the Division conducted RACT analyses to demonstrate that the RACT requirements for CTG and major sources in the DMNFR Area had been fulfilled. The Division conducted these RACT analyses for VOC and NO_X by listing state regulations implementing or exceeding RACT requirements for each CTG or non-CTG category at issue, and by detailing the basis for concluding that these regulations fulfilled RACT, through comparison with established RACT requirements described in the CTG and ACT guidance documents and rules developed by other state and local agencies. The EPA approved the majority of the State's CTG RACT analysis on July 3, 2018.[26]

In July 2018, the Commission adopted categorical RACT requirements for combustion equipment at major sources under the Moderate classification that the Commission had determined in 2016 were not addressed by SIP RACT requirements. In November 2019, the Commission adopted SIP requirements to include provisions that implement RACT for certain CTG VOC source categories in the DMNFR Area. Specifically, the Commission adopted categorical RACT requirements for industrial cleaning solvent and metal furniture surface coating operations. The EPA approved these revisions on February 24, 2021.[27]

The RACT submissions that we are now proposing to approve include those that we have not previously acted on that are addressing RACT for CTG and Moderate non-CTG VOC and NO_X sources and categories. We previously deferred action on these pieces because we determined that Colorado's SIP revisions did not meet major source NO_X RACT for the Moderate classification or miscellaneous metal coatings CTG RACT requirements. On October 14, 2022, Colorado submitted a letter [28] to the EPA committing to correct the deficiencies through rulemaking in December 2022. The Colorado Air Pollution Control Division (Division) has proposed revisions that are consistent with the commitments in the letter.[29] Based on the State's commitment to correcting the deficiencies identified by the EPA, and recognizing the substantial progress made toward fulfilling that commitment, we are now proposing conditional approval of the miscellaneous metal coatings CTG and major source NO_X rules for which we previously deferred action.

B. Evaluation of RACT for Miscellaneous Metal Coatings Sources

As part of its May 31, 2017 submittal, the Division determined that RACT for sources covered by the miscellaneous metal coatings CTG was met through existing Reg. 7 rules that were based on the EPA's 1978 metal coatings CTG. The Division also submitted a negative declaration [30] for the plastic parts coatings limits in Tables 3, 4, 8, and 9 of the 2008 miscellaneous metal coatings CTG.[31] The EPA's 2008

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[18] CAA section 110(a)(2), 42 U.S.C. 7410(a)(2).

[19] 39 CR 15, available at *https://www.sos.state.co.us/CCR/RegisterPdfContents.do?publicationDay=08/10/2016.*

[20] 41 CR 9, available at *https://www.sos.state.co.us/CCR/RegisterPdfContents.do?publicationDay=05/10/2018.*

[21] General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment Areas—Supplement (on Control Techniques Guidelines), 44 FR 53761 (Sep. 17, 1979).

[22] *See https://www.epa.gov/ground-level-ozone-pollution/control-techniques-guidelines-and-alternative-control-techniques* for a list of EPA-issued CTGs and ACTs.

[23] *See* CAA section 182(b)(2), 42 U.S.C. 7511a(b)(2)); *see also* Note, RACT Qs & As—Reasonably Available Control Technology (RACT): Questions and Answers, William Harnett, Director, Air Quality Policy Division, EPA (May 2006), available at *https://www.regulations.gov/document/EPA-R08-OAR-2020-0114-0008.*

[24] *See* CAA sections 182(b), 182(c), 182(d), 182(f)(1), and 302(j).

[25] *See* Memorandum, ''Approval Options for Generic RACT Rules Submitted to Meet the non-CTG VOC RACT Requirement and Certain NO_X RACT Requirements,'' Sally Shaver, Director, Air Quality Strategies & Standards Division, EPA (Nov. 7, 1996), available at *https://www.epa.gov/sites/production/files/2016-08/documents/shavermemogenericract_7nov1996.pdf.*

[26] *See* 83 FR 31068. A negative declaration as to RACT for sources covered by the aerospace CTG was approved on November 5, 2021 (86 FR 61071). Colorado's RACT demonstrations for sources covered by the industrial cleaning solvents, metal furniture coatings (2007), and wood furniture CTGs were approved on February 24, 2021 (86 FR 11127); and the state's RACT demonstration for sources covered by the oil and gas CTG was conditionally approved on May 13, 2022 (87 FR 29228).

[27] 86 FR 11127.

[28] The letter is dated October 13, 2022 and was received on October 14, 2022. *See* ''Colorado Commitment Letter: 2008 Ozone NAAQS Serious SIP'' email from Jessica Ferko, Planning & Policy Program Manager, Colorado Department of Public Health and Environment (in the docket).

[29] *See https://drive.google.com/drive/u/0/folders/1zwYGnKubclWxAcTwOCVhq6xAWlz1FppE.*

[30] States are not required to adopt RACT limits for source categories for which no sources exist in a nonattainment area, and can submit a negative declaration to that effect.

[31] See p. 6–3 of the Moderate ozone attainment plan, contained in the docket.

miscellaneous metal coatings CTG recommends expanded coatings VOC content limits from four to fifty categories and work practices, application methods, and recordkeeping. In response to the EPA's concerns with Colorado's reliance on the EPA's 1978 Metal Coating CTG, Colorado revised the metal surface coating requirements in its May 10, 2019 submittal. In a separate action, the EPA proposes to find that Colorado's submittal for sources subject to VOC coating categories in Tables 2 and 7 of the CTG in the DMNFR Area provides for the implementation of RACT.[32] Additionally, the Division now has committed to adopting VOC content limits for motor vehicle materials reflected in Table 6 of the CTG and associated work practices in Reg. 7, Part C, Section I.P.[33] Finally, the Division is submitting a negative declaration for pleasure craft surface coatings in Table 5 of the CTG.

The Division compared requirements for miscellaneous metal parts coatings to existing Colorado regulations, Federal rules, CTG requirements, information and determinations in the RACT/BACT/LAER Clearinghouse (RBLC), and other state requirements and regulations, and certified that Reg. 7 approved rules demonstrated RACT for Miscellaneous Metal Parts Coatings.[34] We have reviewed Colorado's new and revised VOC rules for the categories covered by the miscellaneous metal coatings CTG and the demonstrations submitted by Colorado, and have compared the emission limitations and control requirements with those of the CTG, Federal rules, information and determinations in the RBLC, and other state requirements and regulations.[35] As previously discussed, we approved the majority of the State's previous submittals as meeting RACT requirements. This proposal is not intended to reopen or revisit any aspect of previous final rules. Section VI includes a detailed discussion of the rules that the EPA is proposing to take action on here. A summary of past actions as they relate to CTG VOC coating categories and limits is contained in Table 1 of this action.

TABLE 1—CTG COATING CATEGORIES AND EPA ACTIONS

CTG coating categories	Colorado submittal date	EPA action
Table 2. Metal Parts and Products VOC Content Limits	May 10, 2019	Proposed Approval Anticipated 2022.[36]
Table 3. Plastic Parts and Products VOC Content Limits	May 31, 2017 (Negative declaration).	Approved 83 FR 31068.
Table 4. Automotive/Transportation and Business Machine Plastic Parts VOC Content Limits.	May 31, 2017 (Negative declaration).	Approved 83 FR 31068.
Table 5. Pleasure Craft Surface Coating VOC Content Limits	Anticipated by June 30, 2023 (Negative declaration).	Conditional Approval.
Table 6. Motor Vehicle Materials VOC Content Limits	Anticipated by June 30, 2023	Conditional Approval.
Table 7. Metal Parts and Products VOC Emission Rate Limits	May 10, 2019	Proposed Approval Anticipated 2022.[37]
Table 8. Plastic Parts and Products VOC Emission Rate Limits	May 31, 2017 (Negative declaration).	Approved 83 FR 31068.
Table 9. Automotive/Transportation and Business Machine Plastic Parts VOC Emission Rate Limits.	May 31, 2017 (Negative declaration).	Approved 83 FR 31068.

C. Evaluation of RACT for Glass Melting Furnaces and Major Sources of NO_X

In preparing its RACT determinations, Colorado reviewed source permits, consulted with Division permitting and enforcement staff involved with each source, and consulted with the sources themselves.[38] Colorado also considered control strategies identified in the CTGs, ACTs, RBLC, EPA's Menu of Control Measures, New Source Performance Standards (NSPS), emission guidelines, National Emission Standards for Hazardous Air Pollutants (NESHAP), and in Colorado's regulations.[39] On May 10, 2019, Colorado submitted RACT rules in Reg. 7 for glass melting furnaces located at major sources of NO_X and VOCs (100 tpy or greater). Based on the EPA's concerns that the rules provided for an exemption from the NO_X emission limit of 1.2 lbs/ton of glass pulled during periods when production fell below 35% maximum designed production,[40] the Division has proposed revised rules that remove this exemption so that the NO_X limit applies during all periods of operation, including abnormally low production, except during the initial startup of a new furnace or an existing furnace after a cold rebuild. During these events, which occur approximately every 10–20 years, natural gas fuel consumption of portable burners used to heat the main furnace(s) is limited and must be recorded and counted toward the existing annual limit for furnaces. Additionally, NO_X emissions from the portable burners will count toward the existing annual ton per year NO_X limit for the furnace. Once heating is switched over to the main furnace, NO_X emissions must be monitored via a continuous emissions monitoring system/continuous emissions rate monitoring system (CEMS/CERMS). Production data will be used to calculate the 30-day rolling average and ensure compliance with the 1.2 lbs NO_X/ton of glass pulled limit. We therefore propose to find that the combination of emission limits in the revised provisions apply continuously during all modes of operation in line with CAA section 302(k).

We have reviewed Colorado's new rules for glass melting furnaces located at major sources of VOC and NO_X and the demonstrations submitted by

[32] Docket ID. EPA–R08–OAR–2022–0632.

[33] Colorado Commitment Letter Serious SIP—2008 Ozone NAAQS, Michael Ogeltree, Director, Air Pollution Control Division, Colorado Department of Public Health and Environment, Oct. 13, 2022 (in the docket for this action).

[34] See p. 6–4 and Appendix 6–B on p. 6–19 of Colorado's 2008 Ozone Moderate Area Attainment Plan for the DMNFR.

[35] *See* the May 2021 EPA TSD included in the docket for this action.

[36] Docket ID. EPA–R08–OAR–2022–0632.

[37] *Id.*

[38] See Colorado's Technical Support Document for Reasonably Available Control Technology for Boilers, Turbines, Engines and Aggregate Kilns at Major NO_X Sources in the DMNFR Nonattainment Area, July 2018. Available within the docket for this action.

[39] See *id.*

[40] See the EPA's June 29, 2018 comments on Colorado's revised draft ozone SIPs for the DMNFR Area, in the docket for this action.

Colorado,[41] and have compared the emission limitations and control requirements with those of Federal rules, consent decrees, information and determinations in the RBLC, and other state requirements and regulations.[42] As previously discussed, we approved the majority of the State's previous submittals as meeting RACT requirements.[43] We also anticipate proposing approval of additional major source RACT requirements in 2022.[44] This proposal is not intended to reopen or revisit any aspect of previously approved rules. Section VI includes a detailed discussion of the rules that the EPA is proposing to take action on here.

D. Proposed RACT Determination for Miscellaneous Metal Coatings CTG and Glass Melting Furnaces at Major Sources of NO_X

Based on our review, and as supported by the State's commitment to develop and submit additional VOC coating content limits and associated work practices, definitions, recordkeeping, and recording requirements for miscellaneous metals coatings and NO_X emission limits for glass melting furnaces at major sources, we propose to conditionally approve the rules included in the State's commitment letter as meeting RACT requirements and providing for the lowest emission limitation through application of control techniques that are reasonably available considering technological and economic feasibility. Therefore, we propose to conditionally approve the rules noted above as satisfying CAA RACT requirements for the miscellaneous metal coatings CTG sources and glass melting furnaces in the DMNFR Area.[45] For more information, see the Technical Support Document (TSD) for this action.

VI. The EPA's Evaluation of SIP Control Measures in the October 13, 2022 Commitment Letter

Reg. 7, Part C, Section I.P., Miscellaneous Metal Coatings

Section I of Part C contains rules for surface coating operations. The revised Section I.P., Motor Vehicle Materials, applies to automotive coating facilities where the total actual VOC emissions from coatings, including cleaning activities, at the facility are greater than or equal to 2.7 tons per 12-month rolling period, before consideration of controls.

Section I.P.2. adds new definitions associated with the requirements in I.P. Section I.P.4. includes new control requirements for automotive coating facilities including reducing VOC emissions with an emission control system having a control efficiency of 90% or greater or complying with the VOC content limits established in Tables 3 of Section I.P. Owners and operators must use and follow application methods and work practice standards in Sections I.P.5 and 6 to reduce VOC emissions. These include the use of high-volume low-pressure spray, roller coat, and airless spray; storing all VOC-containing coatings, thinners, coating-related waste materials, cleaning materials, and used shop towels in closed containers; and minimizing VOC emissions from cleaning of application, storage, mixing, and conveying equipment by cleaning equipment without atomizing the cleaning solvent and capturing spent solvent in closed containers. Section I.P.7. contains recordkeeping requirements to demonstrate compliance with Section I.P. Records must be maintained for a minimum of five years and made available to the Division upon request.

A detailed review of Section I.P. is in the TSD for this action. We propose to find that the provisions in Section I.P. are consistent with CAA requirements, represent RACT for the emission limits in Table 6 ''Motor Vehicle Materials VOC Content Limits'' of the 2008 Miscellaneous Metal Parts and Products CTG, and that they strengthen the SIP. We therefore propose to conditionally approve the revisions in Part C, Section I.P.

Reg. 7, Part E, Section II.A.4.d. Glass Melting Furnaces

Section II of Part E contains rules for the control of emissions from stationary and portable combustion equipment in the DMNFR Area. The Commission revised this section of Reg. 7 to include provisions in the SIP that require the implementation of RACT for glass melting furnaces at major sources of NO_X emissions in Section II.A.4.d. Affected sources must comply with a limit of 1.2 pounds of NO_X per ton of glass pulled on a 30-production-day rolling average. For periods when no glass is pulled, NO_X mass emissions must be calculated and included in the annual mass emissions totals for the furnace. Section II.A.4.d.(ii)(A) limits portable burner fuel use to 8 million standard cubic feet of natural gas during the initial heating phase following an original construction or refractory brick replacement or repair project. NO_X emissions from the use of portable burners must be calculated using the process described in Section II.A.4.d.(ii)(A). SIP-approved Section II.A.5.c.(i)(A)[46] requires continuous emission monitoring to monitor compliance with the applicable emission limit. Records and reporting requirements to demonstrate compliance with Section II.A.4.d. controls are included in SIP-approved Sections II.A.7 and 8.[47]

A detailed evaluation of Section II is in the TSD for this action. We propose to find that the provisions in Section II are consistent with CAA and RACT requirements, and that they strengthen the SIP. We therefore propose to approve the revisions in Part E, Section II.

The revisions described in this section[48] will strengthen the SIP, and (once the State has submitted the revised regulations described in its commitment letter) will meet CAA and RACT requirements. We therefore propose to conditionally approve these revisions into the SIP.

VII. Proposed Action

For the reasons expressed above, the EPA proposes to conditionally approve revisions to Reg. 7, Part C, Section I.P. and Reg. 7, Part E, Section II.A.4. Additionally, the EPA is proposing to conditionally approve Colorado's determination that the Reg. 7 revisions satisfy RACT requirements for the Colorado ozone SIP for the 2008 miscellaneous metal coatings CTG and major source NO_X RACT for the 2008 8-hour Moderate ozone area. Under section 110(k)(4) of the Act, the EPA may approve a SIP revision based on a commitment by a state to adopt specific enforceable measures by a date certain,

[41] See Colorado's Technical Support Document for Reasonably Available Control Technology for Boilers, Turbines, Engines and Aggregate Kilns at Major NO_X Sources in the DMNFR Nonattainment Area, July 2018. See also Colorado's Technical Support Document for Reasonably Available Control Technology for Major Sources Supporting the Denver Metro/North Front Range State Implementation Plan for the 2008 and 2015 8-Hour Ozone National Ambient Air Quality Standards, October 31, 2022. Available within the docket for this action.

[42] *See* the EPA TSD included in the docket for this action.

[43] 86 FR 11125 (Feb. 24, 2021).

[44] *See* docket ID. EPA–R08–OAR–2022–0632.

[45] *See https://www.epa.gov/ground-level-ozone-pollution/ract-information.*

[46] *See https://www.epa.gov/system/files/documents/2021-09/co-table-c.pdf#reg7_parte.*

[47] *Id.*

[48] With the exception of revisions described in the State's commitment letter, which have not been submitted as SIP revisions yet. As previously noted, those revisions will be evaluated in a separate rulemaking after the state submits them to the EPA.

but not later than one year after the date of approval of the plan revision. On October 14, 2022, Colorado submitted a letter committing to adopt and submit specific revisions by June 30, 2023.[49] Specifically, the State has committed to add additional VOC coating content limits and associated work practices, definitions, recordkeeping, and recording requirements for motor vehicle materials, submit a negative declaration for pleasure craft surface coatings, and add NO_X emission limits for glass melting furnaces at major sources. If we finalize our proposed conditional approval, Colorado must adopt and submit the specific revisions it has committed to by June 30, 2023 in order for the conditional approval to convert to full approval. We note that the Division has proposed to adopt the revisions as outlined in the commitment letter at the December 2022 AQCC hearing, and we anticipate that the State will meet its deadline to submit these measures as SIP revisions. However, if Colorado does not comply with its commitment by June 30, 2023, if we find Colorado's SIP submission provided to fulfill the commitment to be incomplete, or if we disapprove the SIP submission, this conditional approval will convert to a disapproval. If any of these occur and our conditional approval converts to a disapproval, that will constitute a disapproval of a required plan element under part D of title I of the Act, which will start an 18-month clock for sanctions [50] and the two-year clock for a Federal implementation plan.[51]

VIII. Consideration of Section 110(l) of the CAA

Under section 110(l) of the CAA, the EPA cannot approve a SIP revision if the revision would interfere with any applicable requirements concerning attainment and reasonable further progress toward attainment of the NAAQS, or any other applicable requirement of the Act. In addition, section 110(l) requires that each revision to an implementation plan submitted by a state shall be adopted by the state after reasonable notice and public hearing.

The Colorado SIP revisions that the EPA is proposing to conditionally approve do not interfere with any applicable requirements of the Act. The Reg. 7 revisions are intended to strengthen the SIP and to serve as RACT for certain sources for the Colorado ozone SIP. We anticipate the submittal to show that the revisions were adopted after reasonable public notices and hearings because the revisions are currently in the public comment phase. Therefore, CAA section 110(l) requirements are satisfied.

IX. Environmental Justice Considerations

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. Additionally, Executive Order 13985 (86 FR 7009, Jan. 25, 2021) directs Federal agencies to assess whether and to what extent their programs and policies perpetuate systemic barriers to opportunities and benefits for underserved populations, and Executive Order 14008 (86 FR 7619, Feb. 1, 2021) directs Federal agencies to develop programs, policies, and activities to address the disproportionate and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities.

To identify potential environmental burdens and susceptible populations in the DMNFR area, a screening analysis was conducted using the EJSCREEN [52] tool to evaluate environmental and demographic indicators within the area, based on available data from the Census Bureau's American Community Survey. The tool outputs showing the results of this assessment are in the docket for this action. These results indicate that within the DMNFR area there are census block groups that are above the national averages and above the 80th percentile (in comparison to the nation as a whole) for the numbers of persons experiencing low income and people of color. These populations may be vulnerable and subject to disproportionate impacts within the meaning of the executive orders described above. Further, as the EJSCREEN analysis is a screening-level assessment and not an in-depth review, it is possible that there are other vulnerable groups within the DMNFR area.

As to all vulnerable groups within the DMNFR area, as explained below we believe that this action will be beneficial and will tend to reduce impacts. When the EPA establishes a new or revised NAAQS, the CAA requires the EPA to designate all areas of the U.S. as either nonattainment, attainment, or unclassifiable. If an area is designated nonattainment for a NAAQS, the state must develop a plan outlining how the area will attain and maintain the standard by reducing air pollutant emissions. In this action we are proposing to conditionally approve state rules as meeting the CAA standard for RACT, which the EPA has defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. Approval of these rules into the SIP will establish federally enforceable requirements that will reduce emissions from coatings and major source emission points in the area. These requirements will contribute to the increased protection of those residing, working, attending school, or otherwise present in those areas, and we propose to determine that this rule, if finalized, will not have disproportionately high or adverse human health or environmental effects on communities with environmental justice concerns.

X. 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 proposing to incorporate by reference Colorado AQCC Regulation 7 pertaining to the control of ozone via ozone precursors and control of hydrocarbons from oil and gas emissions discussed in section VI of this preamble. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

XI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices,

[49] Although CAA section 110(k)(4) allows the EPA to make a conditional approval based on a commitment to act within one year of the final conditional approval, Colorado has committed to act on a much more accelerated schedule.

[50] *See* CAA section 179(a)(2).

[51] *See* CAA section 110(c)(1)(B).

[52] EJSCREEN is an environmental justice mapping and screening tool that provides the EPA with a nationally consistent dataset and approach for combining environmental and demographic indicators; available at *https://www.epa.gov/ejscreen/what-ejscreen.*

provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve 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 (Public Law 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. Accordingly, the proposed 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: November 28, 2022.

KC Becker,

Regional Administrator, Region 8.

[FR Doc. 2022–26291 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 123

[EPA–HQ–OW–2022–0834; FRL–10123–01–OW]

RIN 2040–AG27

NPDES Small MS4 Urbanized Area Clarification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to clarify its National Pollutant Discharge Elimination System (NPDES) Stormwater Phase II regulations due to recent changes made by the Census Bureau. The changes to EPA's regulations would be limited to clarifying that the designation criteria for small municipal separate storm sewer systems (MS4s), which have been used since the promulgation of the regulations in 1999, would remain the same. These clarifications are necessary due to the Census Bureau's recent decision to discontinue its practice of publishing the location of ''urbanized areas'' along with the 2020 Census and future censuses. The clarification in this proposed rulemaking would replace the term ''urbanized area'' in the Phase II regulations with the phrase ''urban areas with a population of at least 50,000,'' which is the Census Bureau's longstanding definition of the term urbanized areas. This change would allow NPDES permitting authorities to use 2020 Census and future Census data in a manner that is consistent with existing longstanding regulatory practice. Because this clarification would maintain the current scope of which entities are regulated as small MS4s, and is not expected to generate opposition, EPA is also publishing the same clarification in the **Federal Register** as a direct final rule. As is EPA's practice for direct final rules, if the Agency receives adverse comments in response to either the direct final rule or this proposed rulemaking, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect and will address public comments received in any final rule action.

DATES: Comments on this proposed rule must be received on or before January 3, 2023.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2022–0834 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 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 ''Written Comments'' heading of the Public Participation section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Huddle, Water Permits Division (MC4203), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington DC 20004; telephone number: (202) 564–7932; email address: *huddle.heather@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposed rulemaking to clarify the NPDES small MS4 urbanized area definition is being published in tandem with a direct final rule published in the ''Rules'' section of the **Federal Register** under the same title. Both this proposed rulemaking and the separate direct final rule would make the same clarification to the Phase II regulations. Both actions are limited to clarifying that EPA will retain the existing threshold for automatic designation of small MS4s for regulation under the Phase II stormwater permitting regulations. The threshold for automatic designation was used following the 2000 and 2010 Censuses and is based on the MS4 being in an urbanized area of 50,000 or more people. Both this proposed rulemaking and the direct final rule actions would maintain the threshold for automatic designations of small MS4s and would ensure that the designation of new MS4s will continue as originally required under the Phase II regulations. EPA explains that the Agency views this as a noncontroversial action and anticipates no adverse comment. However, if EPA receives adverse comment in response to either publication, the Agency will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the direct final rule will

not take effect. EPA would then address public comments as required as part of any subsequent final rule based on the proposed rulemaking.

Table of Contents

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2022–0834, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), 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. 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.

B. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. General Information

A. Does this action apply to me?

Entities potentially regulated by this proposed action include:

Category	Examples of regulated entities	North American industry classification system (NAICS) code
Federal and state government	EPA or state NPDES stormwater permitting authorities	924110
Local governments	Operators of small municipal separate storm sewer systems	924110
State government	State departments of transportation	926120
Military	Federal military bases	928110
Public academic institutions	Publicly-administered colleges, universities, and professional schools	611310

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table includes the types of entities that the EPA is now aware could potentially be regulated by this action. Other types of entities not included 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 122.28, 122.32, and 122.35, and the discussion in the preamble. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is EPA taking?

EPA is proposing to clarify its NPDES Phase II regulations due to recent changes made by the Census Bureau. The proposed changes to EPA's regulations are limited to clarifying that the designation criteria for small MS4s, which have been used since the promulgation of the regulations in 1999, will remain the same. The clarification would be effectuated by replacing the term previously used by the Census Bureau, ''urbanized area,'' with the phrase ''urban areas with a population of at least 50,000,'' which is the Census Bureau's longstanding criteria for defining urbanized areas.

C. What is the Agency's authority for taking this action

The authority for this rulemaking is the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.,* including sections 402 and 501.

D. Background

1. Statutory and Regulatory Overview

Stormwater discharges are subject to regulation under section 402(p) of the Clean Water Act (CWA). Under this provision, Congress required the following stormwater discharges initially to be subject to NPDES permitting requirements: stormwater discharges for which NPDES permits were issued prior to February 4, 1987; discharges ''associated with industrial activity;'' discharges from MS4s serving populations of 100,000 or more; and any stormwater discharge determined by EPA or a state to ''contribute . . . to a violation of a water quality standard or to be a significant contributor of pollutants to waters of the United States.'' Congress further directed EPA to study other stormwater discharges and determine which discharges needed additional controls.

EPA developed the stormwater regulations under section 402(p) of the CWA in two phases, as directed by the statute. In the first phase, under section 402(p)(4) of the CWA, EPA promulgated regulations establishing application and other NPDES permit requirements for stormwater discharges from medium (serving populations of 100,000 to 250,000) and large (serving populations of 250,000 or more) MS4s, and stormwater discharges associated with industrial activity. EPA published the final Phase I rule on November 16, 1990. 55 FR 47990. The Phase I rule, among other things, defined ''municipal separate storm sewer'' as publicly-owned conveyances or systems of conveyances that discharge to waters of the United States and are designed or used for collecting or conveying stormwater, are not combined sewers, and are not part of a publicly-owned treatment works. 40 CFR 122.26(b)(8).

In the second phase, section 402(p)(5) and (6) of the CWA required EPA to conduct a study to identify other stormwater discharges that needed further controls ''to protect water quality,'' report to Congress on the results of the study, and designate for regulation additional categories of stormwater discharges not regulated in Phase I in consultation with state and local officials. EPA promulgated the Phase II rule on December 8, 1999, designating discharges from certain small MS4s and from small construction sites (disturbing equal to or greater than one acre and less than five acres) and requiring NPDES permits for these discharges. 64 FR 68722 (December 8, 1999). A regulated small MS4 is generally defined as any MS4 that is not already covered by the Phase I program and that is located within the ''urbanized area'' boundary as determined by the latest U.S. Decennial Census. 40 CFR 122.32(a)(1) (''you are regulated if you operate a small MS4, including but not limited to systems operated by Federal, State, Tribal, and local governments, including State departments of transportation; and . . . [y]our small MS4 is located in an urbanized area as determined by the latest Decennial Census by the Bureau of the Census.'').

Separate storm sewer systems such as those serving military bases, universities, large hospitals or prison complexes, and highways are also included in the definition of ''small MS4.'' 40 CFR 122.26(b)(16). In addition, the Phase II rule includes authority for EPA (or states authorized to administer the NPDES program) to require NPDES permits for currently unregulated stormwater discharges through a designation process. 40 CFR 122.26(a)(9)(i)(C) and (D). Other small MS4s located outside of an urbanized area may be designated as a regulated small MS4 if the NPDES permitting authority determines that its discharges cause, or have the potential to cause, an adverse impact on water quality. 40 CFR 122.32(a)(2), 123.35(b)(3).

2. History of Using Urbanized Area Population Threshold for Small MS4 Designations

Since the 1950 Census, the Census Bureau has defined ''urbanized area'' as ''one or more cities of 50,000 or more and all the nearby closely settled suburban territory, or urban fringes. '' [1] This definition was in effect when EPA promulgated the Phase II Rule in 1999, and for the two censuses (2000 and 2010 Census) that have been published since then.[2] The Census Bureau's use of this population threshold is significant for the Phase II permit program because where an MS4 is located within an area identified in the latest decennial Census as having a minimum population of 50,000 or more people (*i.e.,* in an ''urbanized area''), the MS4 is automatically designated as regulated under the Phase II regulations.

The Phase II regulations have referred to the term ''urbanized area'' since the small MS4 program's inception and this term has always been used synonymously with the 50,000 population threshold. When EPA initially promulgated the Phase II regulations, EPA explained that it was adopting the Census Bureau's definition of ''urbanized area'' as one of the designation criteria for small MS4s and provided a definition of ''urbanized area'' that was identical to the Census Bureau's definition. EPA stated in the preamble to the Phase II rule that ''[u]nder the Bureau of the Census definition of 'urbanized area,' adopted by EPA for the purposes of this final rule, 'an urbanized area (UA) comprises a place and the adjacent densely settled surrounding territory that together have a minimum population of 50,000 people.''' 64 FR 68722, 68751 (December 8, 1999).

EPA acknowledged that the Census Bureau could in the future change the criteria by which it defines ''urbanized area,'' which would then in turn affect the way in which new small MS4s would be automatically designated. It is for this reason that EPA explained in the Phase II rule preamble that new MS4 designations ''will be governed by the Bureau of the Census' definition of an urbanized area in effect for that year.'' 64 FR 68722, 68751 (December 8, 1999). However, the Census Bureau has not changed the 50,000 population threshold since they adopted it 70 years ago. From the small MS4 permit program's inception in 1999, therefore, EPA and state permitting authorities have always relied on the 50,000 population threshold to automatically designate and regulate MS4s. It is only now with the 2020 Census that the Census Bureau has announced its decision to no longer separately identify ''urbanized areas.'' 87 FR 16706, 16707 (March 24, 2022).

III. Rationale and Summary of Proposed Rule

A. Why a Change to the Phase II Regulations Is Appropriate

This section explains how the Census Bureau's elimination of the term ''urbanized area'' relates to which MS4s are automatically designated for regulation under the Phase II regulations based on the 2020 Census and subsequent censuses.

The Census Bureau's elimination of the term ''urbanized area'' does not

[1] *1950 Census of Population—Preliminary Counts, Population of Urbanized Areas: April 1, 1950,* U.S. Department of Commerce, Bureau of the Census. Series PC–3 No. 9. February 1, 1951. See *https://www2.census.gov/library/publications/decennial/1950/pc-03/pc-3-09.pdf.*

[2] Urbanized areas have been defined by the Census Bureau as ''urban areas that contain 50,000 or more people . . .''. See 76 FR 53030, 53039 (August 24, 2011); and 67 FR 11663, 116667 (March 15, 2002).

impact small MS4s that are already regulated under the Phase II rule. For those small MS4s already regulated because of their location in an ''urbanized area'' designated by a previous census, the Phase II regulatory history indicates that a subsequent Census Bureau change to the designation criteria for urbanized areas does not affect their regulatory status. EPA stated in the Phase II rule preamble that even if the Census Bureau were to change its ''urbanized area'' definition, ''a small MS4 that is automatically designated into the NPDES program for storm water under an urbanized area calculation for any given Census year will remain regulated regardless of the results of subsequent urbanized area calculations.'' 64 FR 68722, 68751 (December 8, 1999).[3] EPA's regulations, therefore, require continued regulation of previously designated small MS4s despite the Census Bureau's change. EPA notes that this does not prevent the operator of a qualifying MS4 so designated from requesting consideration of an NPDES waiver under 40 CFR 122.32(c).

The existing Phase II regulatory text does not explicitly instruct EPA how to treat the designation of new MS4s due to the fact that the Census Bureau's decennial censuses will no longer separately identify ''urbanized areas.'' For the 1999 Phase II rule, EPA always intended the universe of regulated small MS4s to grow in a manner commensurate with the growth of ''urbanized areas'' as identified by the latest decennial census. However, while the Phase II rule preamble explained that new MS4s would be designated in accordance with the latest census definition of ''urbanized area,'' it did not provide instruction on what to do if a decennial census no longer identifies the location of such urbanized areas. EPA is proposing this action to address the Census Bureau's changes and clarify for permitting authorities and the public that it intends the scope of which small MS4s are regulated to not change, and that it would rely on what that term has always meant rather than having the regulations reference an out-of-date term.

B. Rationale for Proposed Clarification to Phase II Regulations

The most straightforward way for EPA to clarify its regulations in a manner that maintains program continuity and consistency is to replace the reference to ''urbanized area'' in the Phase II regulations with text that replicates the 50,000 population threshold on which the Census Bureau and NPDES authorities have historically relied. As discussed in Section II.D.2 of this preamble, from the inception of the small MS4 permitting program, the 50,000 population threshold has been used synonymously with the term ''urbanized area'' by both the Census Bureau and NPDES permitting authorities. Replacing the term ''urbanized area'' with text that incorporates this same 50,000 population threshold would mean that the existing method for designating small MS4s following the latest decennial census would be identical to how it has always been implemented. This proposed change would thus ensure that there is no disruption in the designation of new MS4s and that the program would be implemented in a historically consistent manner.

Substituting the obsolete references to ''urbanized areas'' with the 50,000 population threshold would also ensure that new Census 2020 mapping data and subsequent census mapping data can be used seamlessly to identify newly regulated MS4s. Prior to the recent Census Bureau changes, the location of any ''urbanized areas'' would have been automatically identified with any decennial census. Moving forward, however, each decennial census will be limited to identifying ''urban areas'' without identifying ''urbanized areas'' within those areas. Even though ''urbanized area'' locations will no longer be provided as part of the 2020 Census and future censuses, the Census Bureau will continue to provide population data for each identified urban area.[4] The availability of these population data will enable EPA and state permitting authorities to easily identify which urban areas have populations of 50,000 or more people and, therefore, to provide the necessary information to designate new MS4s.

C. Summary of Proposed Changes to Phase II Regulations

The proposed changes to the Phase II regulations are limited to replacing the existing references to ''urbanized area'' as a criterion for designating small MS4s for regulation with text that incorporates the underlying population threshold associated with that term, or more specifically ''urban areas with a population of 50,000 or more people.'' This change would be made in the following specific sections:

- *40 CFR 122.28(a)(1)(vi):* This provision describes the requirement that general permits can only be used to provide coverage to discharges in a specific geographic area. The change here would be to the existing list of examples of geographic or political boundary areas that meet this requirement, which currently refer to ''urbanized areas'' as one of the examples. The reference to ''urbanized areas'' here would be replaced by the described 50,000 population threshold.
- *40 CFR 122.32(a)(1):* This provision currently specifies that small MS4s located in ''urbanized areas'' are regulated as small MS4s. The reference to ''urbanized areas'' here would be replaced by the described 50,000 population threshold.
- *40 CFR 122.32(d):* This provision indicates that small MS4s regulated under 40 CFR 122.32(a)(1) for ''urbanized areas'' may be eligible for an NPDES waiver if they meet the applicable criteria. The reference to ''urbanized areas'' here would be substituted with a reference to the revised text in 40 CFR 122.32(a)(1).
- *40 CFR 122.33(b)(3):* This provision references the ability of regulated small MS4s located in the same ''urbanized area'' as a medium or large MS4 to be included as a limited co-permittee in the same NPDES permit as the medium or large MS4. The reference to ''urbanized area'' would be modified to read ''urban area'' instead.
- *40 CFR 123.35(b)(1)(ii):* This provision includes a reference to an ''urbanized area'' in the context of regulatory guidance on criteria that state permitting authorities may use to designate other small MS4s for regulation, including ''contiguity to an urbanized area.'' The reference to

[3] EPA's statement in its entirety: ''Based on historical trends, EPA expects that any area determined by the Bureau of the Census to be included within an urbanized area as of the 1990 Census will not later be excluded from the urbanized area as of the 2000 Census. However, it is important to note that even if this situation were to occur, for example, due to a possible change in the Bureau of the Census' urbanized area definition, a small MS4 that is automatically designated into the NPDES program for storm water under an urbanized area calculation for any given Census year will remain regulated regardless of the results of subsequent urbanized area calculations.''

[4] In its *2020 Urban Areas Frequent Asked Questions,* the Census Bureau provided the following answer in response to the question ''Is it true that the Census Bureau is no longer defining urbanized areas?'': ''No. The Census Bureau will no longer identify an individual urban area as either an urbanized area or an urban cluster. We will refer to all areas as ''urban areas'' regardless of population size. *We will publish population and housing counts for each urban area when we announce results of the 2020 Census urban area delineation. Data users and program will be able to use those counts and subsequent American Community Survey estimates to categorize urban areas according to population size.*'' (emphasis added) See *https://www2.census.gov/geo/pdfs/reference/ua/2020_Urban_Areas_FAQs.pdf.*

''urbanized area'' would be replaced by the described 50,000 population threshold.

• *40 CFR 123.35(b)(2):* This provision includes a reference to an ''urbanized area'' in the context of applying state permitting authority criteria for designating additional small MS4s for regulation, including MS4s located outside of an ''urbanized area'' serving a jurisdiction with a population density of at least 1,000 people per square mile and a population of at least 10,000. The reference to ''urbanized area'' would be replaced by the described 50,000 population threshold.

• *40 CFR 123.35(d)(1):* This provision indicates that small MS4s regulated under 40 CFR 122.32(a)(1) for ''urbanized areas'' may be eligible for an NPDES waiver if they meet the applicable criteria. The reference to ''urbanized areas'' here would be substituted with the described 50,000 population threshold.

D. Costs of This Proposed Action

The regulatory clarifications in this proposed rulemaking would ensure that the population basis for regulating small MS4s remain the same. As a result, these clarifications would not result in increased costs to small MS4 permittees or to state and EPA permitting programs, nor would it regulate additional MS4s beyond what was required by the 1999 Phase II regulations.

E. Implementation and Technical Assistance

If no adverse comments are received in response to the direct final rule or this proposed rulemaking, the changes made by the direct final rule will become effective on March 2, 2023.

EPA plans to continue to provide technical assistance to permitting authorities in a number of different ways to help with the implementation of the MS4 program following publication of the new census data. The following is a summary of EPA's planned technical assistance activities:

• *Publish new MS4 mapping information:* Following the publication of the 2020 Census urban area information, EPA will be able to determine which urban areas have a population of 50,000 or more people and thereby identify which areas meet the revised rule's criteria for small MS4s. EPA plans to use the 2020 Census data to publish mapping information that will show where urban areas with a population of 50,000 or more people are located in the United States and where these areas are located with respect to municipal boundaries. This information will enable permitting authorities to determine which jurisdictions are likely operating MS4s within urban areas that meet the 50,000 population threshold. EPA also plans to provide mapping information that compares the 2010 Census and 2020 Census location of these urban areas. Permitting authorities will be able to use this information to pinpoint the location of new MS4s and compare how the urban area boundaries have changed since the 2010 Census for existing MS4s.

• *Provide permitting authorities with a draft list of new MS4s:* To assist NPDES permitting authorities, EPA plans to use the mapping information described under the previous bullet point to preliminarily identify new MS4s that are located within the urban areas meeting the population threshold. EPA provided a similar list of new MS4s following the 2010 Census. Permitting authorities are then free to evaluate the MS4s identified on this list to determine if they are accurate and whether any changes are needed.

• *Provide guidance materials:* EPA will provide additional guidance related to the process of permitting newly designated MS4s that NPDES authorities may choose to use. EPA provided similar guidance following the publication of the 2010 Census, which included tips on the suggested steps to follow from initial contact with the new MS4 operators to including them in the applicable NPDES permit. EPA also provided a letter template that permitting authorities could use to inform new MS4 operators of their designation and what to expect from the permitting process moving forward. The Agency plans to update these materials for the 2020 Census, and to explore what additional technical assistance may be needed. EPA will engage with its Federal and State permitting authority partners to determine which type of assistance may be the most beneficial.

• *Rescind interim guidance:* Earlier this year, EPA published on its website *Interim Guidance on Census Elimination of ''Urbanized Areas''* (see *https://www.epa.gov/npdes/interim-guidance-census-elimination-urbanized-area-definition*). The guidance was intended to provide interim recommendations to permitting authorities regarding the implementation of their small MS4 permitting programs following the finalization of the Census Bureau's designation criteria changes while EPA evaluated how best to clarify its regulations. If the direct final rule becomes effective on March 2, 2023 due to the lack of adverse comments, the interim guidance will no longer be necessary and will be rescinded.

VI. Statutory and Executive Orders Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2040–0004. This rule contains no new requirements for reporting and recordkeeping.

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. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule has no net burden on the small entities subject to the rule. EPA is limiting its proposed changes to substituting use of the term ''urbanized area'' in the four subsections of the Phase II regulations with the underlying population criteria that has been used synonymously with this term since the 1999 promulgation of the regulations. See discussion in Sections III.B and C of this preamble. Although making this proposed clarification is important to ensure program continuity and consistency, EPA views this change as akin to a clerical correction to remove an obsolete term and ensure that program applicability remains unchanged. The Agency has therefore concluded that this proposed action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in

UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments, or the private sector.

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 does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

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

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

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

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 people of color, low-income populations, and/or indigenous peoples. This action makes a technical clarification to a previously promulgated regulatory action, and will not change the human health and environmental conditions that currently exist with the implementation of the Phase II regulations.

The EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This regulatory action is a technical clarification to a previously promulgated regulatory action and does not have any disproportionate and adverse impact on people of color, low-income populations and/or indigenous peoples.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 122

Environmental protection, Stormwater, Water pollution.

40 CFR Part 123

Environmental protection, Stormwater, Water pollution.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR parts 122 and 123 as set forth below:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 2. Amend § 122.28 by revising paragraph (a)(1)(vi) to read as follows:

§ 122.28 General permits (applicable to State NPDES programs, see § 123.25).

(a) * * *

(1) * * *

(vi) Urban areas with a population of 50,000 or more people as determined by the latest Decennial Census by the Bureau of the Census; or

* * * * *

■ 3. Amend § 122.32 by revising paragraph (a)(1) and paragraph (d) introductory text to read as follows:

§ 122.32 As an operator of a small MS4, am I regulated under the NPDES storm water program?

(a) * * *

(1) Your small MS4 is located in an urban area with a population of 50,000 or more people as determined by the latest Decennial Census by the Bureau of the Census. (If your small MS4 is not located entirely within an urban area with a population of 50,000 or more people, only the portion that is within this urban area is regulated); or

* * * * *

(d) The NPDES permitting authority may waive permit coverage if your MS4 serves a population of less than 1,000 within the urban area identified in paragraph (a)(1) of this section and you meet the following criteria:

* * * * *

■ 4. Amend § 122.33 by revising paragraph (b)(3) to read as follows:

§ 122.33 Requirements for obtaining permit coverage for regulated small MS4s.

* * * * *

(b) * * *

(3) *Co-permittee alternative.* If the regulated small MS4 is in the same urban area as a medium or large MS4 with an NPDES storm water permit and that other MS4 is willing to have the small MS4 operator participate in its storm water program, the parties may jointly seek a modification of the other MS4 permit to include the small MS4 operator as a limited co-permittee. As a limited co-permittee, the small MS4 operator will be responsible for compliance with the permit's conditions applicable to its jurisdiction. If the small MS4 operator chooses this option it must comply with the permit application requirements of § 122.26, rather than the requirements of § 122.33(b)(2)(i). The small MS4 operator does not need to comply with the specific application requirements of § 122.26(d)(1)(iii) and (iv) and (d)(2)(iii) (discharge characterization). The small MS4 operator may satisfy the requirements in § 122.26 (d)(1)(v) and

(d)(2)(iv) (identification of a management program) by referring to the other MS4's storm water management program.

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

■ 5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 6. Amend § 123.35 by revising paragraphs (b)(1)(ii), (b)(2), and (d)(1) introductory text to read as follows:

§ 123.35 As the NPDES Permitting Authority for regulated small MS4s, what is my role?

* * * * *

(b) * * *

(1) * * *

(ii) *Guidance:* For determining other significant water quality impacts, EPA recommends a balanced consideration of the following designation criteria on a watershed or other local basis: discharge to sensitive waters, high growth or growth potential, high population density, contiguity to an urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census, significant contributor of pollutants to waters of the United States, and ineffective protection of water quality by other programs;

(2) Apply such criteria, at a minimum, to any small MS4 located outside of an urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census serving a jurisdiction with a population density of at least 1,000 people per square mile and a population of at least 10,000;

* * * * *

(d) * * *

(1) You may waive permit coverage for each small MS4s in jurisdictions with a population under 1,000 within the urban area with a population of 50,000 people or more as determined by the latest Decennial Census by the Bureau of the Census where all the following criteria have been met:

* * * * *

[FR Doc. 2022–26227 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 170

[EPA–HQ–OPP–2022–0133; FRL–8528–02–OCSPP]

RIN 2070–AK92

Notification of Submission to the Secretary of Agriculture; Pesticides; Agricultural Worker Protection Standard; Reconsideration of the Application Exclusion Zone Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Draft proposed rule; notification of submission to the Secretary of Agriculture.

SUMMARY: This document notifies the public as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that the EPA Administrator has forwarded to the Secretary of the United States Department of Agriculture (USDA) a draft proposed rulemaking document concerning ''Pesticides; Agricultural Worker Protection Standard; Reconsideration of the Application Exclusion Zone Amendments (RIN 2070–AK92).'' The draft regulatory document is not available to the public until after it has been signed and made available by EPA.

DATES: See Unit I. under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0133, is available at *https://www.regulations.gov.* The docket contains historical information and this **Federal Register** document; it does not contain the draft proposed rule.

FOR FURTHER INFORMATION CONTACT: Aidan Black, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–2381; email address: *black.aidan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

FIFRA section 25(a)(2)(A) requires the EPA Administrator to provide the Secretary of USDA with a copy of any draft proposed rule at least 60 days before signing it in proposed form for publication in the **Federal Register**. The draft proposed rule is not available to the public until after it has been signed by EPA. If the Secretary of USDA comments in writing regarding the draft proposed rule within 30 days after receiving it, then the EPA Administrator shall include the comments of the Secretary of USDA and the EPA Administrator's response to those comments with the proposed rule that publishes in the **Federal Register**. If the Secretary of USDA does not comment in writing within 30 days after receiving the draft proposed rule, then the EPA Administrator may sign the proposed rule for publication in the **Federal Register** any time after the 30-day period.

II. Do any statutory and Executive Order reviews apply to this notification?

No. This document is merely a notification of submission to the Secretary of USDA. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in 40 CFR Part 170

Environmental protection, Agricultural worker, Employer, Farms, Forests, Greenhouses, Nurseries, Pesticide handler, Pesticides, Worker protection standard.

Dated: November 28, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–26296 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2021–0847; FRL–9972–01–OCSPP]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (22–1.5e)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to Orders issued by EPA pursuant to TSCA. The SNURs would require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use,

under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required in association with that determination.

DATES: Comments must be received on or before January 3, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0847, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4163; email address: *wysong.william@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. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use any of the chemical substances contained in this proposed rule. 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:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after January 3, 2023 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) for certain chemical substances that were the subject of PMNs. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of any of these chemical substances for an activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur.

The docket for these proposed SNURs, identified as docket ID number EPA–HQ–OPPT–2021–0847, includes information considered by the Agency in developing these proposed SNURs.

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). These requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register,** a statement of EPA's findings.

For each proposed SNUR containing significant new uses not based on the Order requirements as described in Unit III., EPA is proposing that the general reporting exemption described in 40 CFR 721.45(i) not apply. 40 CFR 721.45(i) provides that the notification requirements of 40 CFR 721.25 do not apply, unless otherwise specified in a specific SNUR, if: ''The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart E of this part, abiding by the provision of the

section 5(e) order exempts the person from submitting a significant new use notice for that specific significant new use.'' EPA is proposing to make that exemption inapplicable to each SNUR in this proposed rule with significant new uses not based on Order requirements to ensure that persons subject to the Order would also be subject to the significant new use notification requirements in this proposed rule that are not based on Order requirements.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four TSCA section 5(a)(2) factors listed in this unit.

The proposed rules include PMN substances that are subject to Orders issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), and in some cases also under TSCA section 5(e)(1)(A)(ii)(II). The TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify significant new uses as any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4). The proposed rules also include other significant new uses EPA proposes to determine are not ongoing based on information showing that the chemical is either not on the TSCA Inventory or had limited Chemical Data Reporting (CDR) under TSCA section 8(a).

IV. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit V. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow the TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors—not just the original submitter—are held to the same standard.

EPA did not previously issue SNURs following these Orders. EPA is now proposing these SNURs to require notice to EPA by any other person who wishes to manufacture or process the chemical substance in a way that does not conform to the protective measures contained in the Order.

The proposed SNURs also include significant new uses EPA proposes to determine are not ongoing based either on information showing that the chemical is not on the TSCA Inventory or based on EPA's review of CDR reporting submissions under TSCA section 8(a). EPA believes that these uses could significantly increase the magnitude and duration of exposure to humans and the environment to these chemical substances. Accordingly, EPA wants the opportunity to evaluate and manage risks, where appropriate, from activities associated with those uses, before manufacturing or processing for those uses were to begin.

If a notice of commencement had not been received for the chemical and it is not on the TSCA Inventory, the proposed SNUR includes a significant new use for uses other than as described in the PMN, and annual production volume greater than 2500 pounds. If the chemical is on the TSCA Inventory, EPA conducted a search of CDR reporting for the chemical in the 2020 reporting cycle. If there was no CDR reporting for the chemical in the 2020 reporting cycle, the proposed SNUR includes significant new uses for use other than as described in the PMN and annual production volume greater than the threshold for CDR reporting for chemicals subject to a TSCA section 5(e) order which is 2500 pounds. If there is CDR reporting for the chemical from the 2020 reporting cycle, the proposed SNUR includes significant new uses for use other than reported in CDR.

This proposed rule advances one of the ''key actions'' in the PFAS Strategic Roadmap where EPA stated it plans to revisit past PFAS regulatory decisions and address those that are insufficiently protective by imposing additional notification requirements. In this way, the Agency can ensure it has the opportunity to review PFAS before they are used in new ways that might present concerns. To view the PFAS Strategic Roadmap and learn more about EPA actions to address PFAS, please visit *https://www.epa.gov/pfas/epa-actions-address-pfas* and *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.*

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
- To identify as significant new uses, other specific uses and production volumes that are not ongoing uses and that could result in changes to the type, form, magnitude, or duration of exposure of human beings or the environment to these chemical substances.
- To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination before the described significant new use of the chemical substance occurs.

V. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for certain chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance that is

identified in this unit as subject to this proposed rule:

- PMN number (the proposed CFR citation assigned in the regulatory text section of the proposed rule).
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities) or Accession number (if assigned for confidential chemical identities).
- Effective date of and basis for the TSCA section 5(e) Order.
- Potentially Useful Information.

The chemicals subject to these proposed SNURs are as follows:

PMN Number: P–00–1085 (40 CFR 721.11716).

Chemical Name: Fluoroacrylate copolymer (generic).

CAS or Accession Number: Accession No. 249720.

Effective Date of TSCA Order: February 6, 2001.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a surfactant. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on comparison to analogous chemical substances, EPA predicted toxicity to aquatic organisms may occur at acute concentrations that exceed 100 ppb. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required:

- No manufacture of the PMN substance beyond 29 months without submittal to EPA of the results of certain testing described in the Testing section of the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication requirements. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a surfactant in paint and coatings manufacturing.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Number: P–01–584 (40 CFR 721.11717).

Chemical Name: Perfluoroalkylsulfonamidoalkyl acrylate, polymer with acrylic acid derivatives (generic).

CAS or Accession Number: Accession No. 254456.

Effective Date of TSCA Order: October 3, 2001.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a surfactant. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on comparison to analogous chemical substances, EPA predicted toxicity to aquatic organisms may occur at acute concentrations that exceed 100 ppb. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required:

- No manufacture of the PMN substance beyond 29 months without submittal to EPA of the results of certain testing described in the Testing section of the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication requirement. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a surfactant in adhesive and synthetic rubber manufacturing.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on a confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Number: P–02–16 (40 CFR 721.11718).

Chemical Name: Urethane polymer modified with perfluoroalkylsulfonamide (generic).

CAS or Accession Number: Accession No. 252290.

Effective Date of TSCA Order: January 30, 2002.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a protective coating. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these

degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a finishing agent in textiles, apparel, and leather manufacturing.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–02–195 (40 CFR 721.11719).

Chemical Name: Urethane polymer modified with perfluoroalkylsulfonamide and polyethoxylate (generic).

CAS or Accession Number: Accession No. 271739.

Effective Date of TSCA Order: May 2, 2002.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a protective treatment. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required:

- Submit to EPA the results of certain testing described in the Testing section of the Order at least 14 weeks before manufacturing or importing the confidential volume listed in the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a finishing agent in textiles, apparel, and leather manufacturing.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on the confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Number: P–02–609 (40 CFR 721.11720).

Chemical Name: Urethane polymer modified with perfluoroalkylsulfonamide (generic).

CAS or Accession Number: Accession No. 279755.

Effective Date of TSCA Order: July 22, 2002.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a protective coating. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as an anti-stain agent.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the

Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–02–700 (40 CFR 721.11721).

Chemical Name: Copolymer of perfluoroalkylsulfonamidoalkyl acrylate and alkyl acrylate modified fatty acid dimers (generic).

CAS or Accession Number: Accession No. 259360.

Effective Date of TSCA Order: August 28, 2002.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a protective coating. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a finishing agent in textiles, apparel, and leather manufacturing.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–02–891 (40 CFR 721.11722).

Chemical Name: Phosphonium, triphenyl(phenylmethyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

CAS or Accession Number: CAS No. 332350–93–3.

Effective Date of TSCA Order: July 15, 2003.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a cure catalyst. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on 8(e) test data on analogous chemical substances, EPA had identified concerns for possible acute lethality. Based on comparison to analogous chemical substances, EPA predicted toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb;
- Use of the PMN substance only for the confidential use as stated in the PMN; and
- Establishment of certain hazard communication requirements.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity, chronic ecotoxicity, and environmental fate testing performed on the confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–02–920 (40 CFR 721.11223).

Chemical Name: Alkane carboxylic acids esters with long chain fatty alcohol and fluorinated alkylsulfonamidoalkyl alcohol (generic).

CAS or Accession Number: Accession No. 257922.

Effective Date of TSCA Order: March 25, 2003.

Basis for TSCA Order: The PMN stated that the use will be as an additive. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as an additive; and
- Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, acute and chronic human health toxicity, acute and chronic ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the

Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–03–32 (40 CFR 721.11724).

Chemical Name: Blocked fluorochemical urethane (generic).

CAS or Accession Number: Accession No. 234152.

Effective Date of TSCA Order: June 26, 2003.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a protective treatment. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on test data on structurally similar chemicals, EPA had identified concerns for lung toxicity and irritation to the eyes and mucous membranes. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a protective treatment; and
- Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of human health toxicity, ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–03–33 (40 CFR 721.11725).

Chemical Name: Polyperfluoro alkylene glycol, perfluoroalkoxy- and hydroxy alkyl amido perfluoroalkyl terminated (generic).

CAS or Accession Number: Accession No. 242467.

Effective Date of TSCA Order: June 26, 2003.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a chemical intermediate. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on test data on structurally similar chemicals, EPA had identified concerns for liver toxicity, acute toxicity, developmental and reproductive toxicity, and cancer. Based on waterproofing of the lungs if respirable aerosols are inhaled, EPA had also identified concerns for chronic lung effects. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order required:

- No manufacture of the PMN substance with an average molecular weight (MW) less than 1000 daltons, more than 5 percent oligomeric material less than 500 daltons or more than 10 percent oligomeric material less than 1000 daltons;
- Analyzing the molecular weight of the PMN substance produced at each facility; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a chemical intermediate; and
- Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–03–67 (40 CFR 721.11726).

Chemical Name: Fluoroalkene substituted alkene polymer (generic).

CAS or Accession Number: Not available.

Effective Date of TSCA Order: July 24, 2003.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a paint additive. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on data on analogous perfluorinated compounds and the high molecular weight of the PMN substance, EPA had also identified concerns for lung effects through lung overload. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order required:

- Manufacture of the PMN substance as an alternating copolymer made up of the confidential monomers specified in the Order to prevent creation of long-chain perfluorinated acids including PFOA;
- Analysis of representative samples of the PMN substance or measurement of initial concentrations of reactants as specified in the Order to ensure compliance with the chemical composition requirements; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures. Additionally, the proposed SNUR

would designate the following as significant new uses:

- Use other than as a paint additive; and
- Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of physical/chemical, chronic human health toxicity, and environmental fate testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–03–77 (40 CFR 721.11727).

Chemical Name: Phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

CAS or Accession Number: CAS No. 332350–93–3.

Effective Date of TSCA Order: July 15, 2003.

Basis for TSCA Order: The PMN stated that use will be as a cure catalyst. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on comparison to analogous chemical substances, EPA had identified concerns for liver toxicity, developmental and reproductive effects, and irritation to mucous membranes, lungs, and eye. Based on comparison to analogous cationic surfactants, EPA predicted concern for toxicity to aquatic organisms. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required the establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of this protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a cure catalyst or chemical intermediate.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of human health toxicity, ecotoxicity, and environmental fate testing performed on confidential analog of the PMN substance may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Numbers: P–04–174 (40 CFR 721.11728) and P–04–176 (40 CFR 721.11729).

Chemical Names: Fluoroacrylate modified urethane (generic) (P–04–174) and Fluorinated oligomer alcohol (generic) (P–04–176).

CAS or Accession Numbers: Accession Nos. 238427 (P–04–0174) and 236181 (P–04–0176).

Effective Date of TSCA Order: October 26, 2005.

Basis for TSCA Order: The PMNs stated that the generic (non-confidential) use of P–04–174 will be as a protective coating and the use of P–04–176 will be as a chemical intermediate. Based on potential degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order required:

- Submit to EPA the results of certain testing on P–04–174 described in the Testing section of the Order at least 14 weeks before manufacturing or importing the total confidential volume of both P–04–174 and P–04–176 combined listed in the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a protective coating (P–04–174) or a chemical intermediate (P–04–176).
- Manufacture beyond an annual production volume of 2500 lbs (P–04–174).

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity and chronic ecotoxicity testing performed on the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Numbers: P–05–75 (40 CFR 721.11731), and P–05–107 (40 CFR 721.11732).

Chemical Names: Perfluoroalkylethyl methacrylate copolymer (generic) (P–05–75) and Perfluoroalkylethyl methacrylate copolymer organic acid salt (generic) (P–05–107).

CAS or Accession Numbers: Accession Nos. 257171 (P–05–107) and 245831 (P–05–75).

Effective Date of TSCA Order: January 5, 2006.

Basis for TSCA Order: The PMNs stated that the generic (non-confidential) uses will be as a textile chemical (P–05–75) and paper/textile chemical (P–05–107). Based on potential degradation products, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on comparison to analogous perfluorinated chemicals, EPA had identified concerns for lung effects under some conditions of use—particularly non-industrial, commercial, or consumer use. Based on potential persistent degradation products, EPA predicted high concern for possible environmental effects. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order required:

- Submit to EPA the results of certain testing described in the Testing section of the Order at least 14 weeks before manufacturing or importing the total confidential volume of P–04–213, P–05–75, and P–05–107 combined listed in the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication protective measure. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as finishing agents in textiles, apparel, and leather manufacturing. *Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity and chronic ecotoxicity testing performed on the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Number: P–04–289 (40 CFR 721.11733).

Chemical Name: Ethylene-tetrafluoroethylene-fluorinated alkene copolymer (generic).

CAS or Accession Number: Accession No. 258981.

Effective Date of TSCA Order: November 5, 2005.

Basis for TSCA Order: The PMN stated that the use will be as a copolymer for automotive and industrial parts. Based on potential incineration, decomposition, and degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required:

- Chemical synthesis of the substance and analysis of the substance demonstrating compliance with the required synthesis according to the confidential conditions in the Chemical Synthesis and Composition section of the Order; and
- Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures. Additionally, the proposed SNUR would designate the following as significant new uses:

- Use other than as a copolymer for automotive and industrial parts; and
- Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of impurity data on the starting material and product and information concerning the manufacture process or other verification that the products do not contain long chain perfluorinated acids may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

PMN Number: P–04–537 (40 CFR 721.11334).

Chemical Name: Fluorochemical ester (generic).

CAS or Accession Number: Accession No. 264949.

Effective Date of TSCA Order: April 21, 2005.

Basis for TSCA Order: The PMN stated that the generic (non-confidential) use will be as a polymer additive. Based on potential incineration, decomposition, and degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance. To protect against these risks, the Order required:

- Submit to EPA the results of certain testing described in the Testing section of the Order at least 14 weeks before manufacturing or importing the

aggregate confidential volume listed in the Order; and

• Establishment of certain hazard communication requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the hazard communication protective measures. Additionally, the proposed SNUR would designate the following as significant new uses:

• Use other than as a finishing agent in textiles, apparel, and leather manufacturing or as a chemical intermediate.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity and chronic ecotoxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

PMN Numbers: P–05–491 (40 CFR 721.11735), P–05–492 (40 CFR 721.11736), P–05–503 (40 CFR 721.11737), P–05–504 (40 CFR 721.11738), P–05–505 (40 CFR 721.11739), P–05–838 (40 CFR 721.11740), P–06–206 (40 CFR 721.11741), P–06–207 (40 CFR 721.11742), P–06–208 (40 CFR 721.11743), P–06–211 (40 CFR 721.11744), P–06–212 (40 CFR 721.11745), P–06–213 (40 CFR 721.11746), P–06–214 (40 CFR 721.11747), P–06–215 (40 CFR 721.11748), P–06–216 (40 CFR 721.11749), P–06–217 (40 CFR 721.11750), and P–06–224 (40 CFR 721.11751).

Chemical Names: Fluoroalkylacrylate copolymer (generic) (P–05–491, P–05–492, P–05–504, P–05–505, P–05–838, P–06–207, P–06–208, P–06–211, P–06–212, P–06–213, P–06–214, P–06–215, P–06–216, P–06–217, and P–06–224), Fluorochemical urethane; (generic) (P–05–503), and Fluoroalkyl acrylate (generic) (P–06–206).

CAS or Accession Numbers: Not Available.

Effective Date of TSCA Orders: May 1, 2006.

Basis for TSCA Order: The PMNs stated that the generic (non-confidential) uses will be as textile treatment additives (P–05–491, P–05–492, P–05–505, P–05–838, P–06–207, P–06–208, P–06–211, P–06–215, P–06–217, and P–06–224), carpet treatment additive (P–05–503, P–06–213, and P–06–216), tile surface treatment (P–05–504), monomer for textile treatment additive (P–06–206), nonwoven internal additive (P–06–212) and paper treatment additive (P–06–214). Based on potential incineration and degradation products, byproducts, unreacted material, and low molecular weight species, EPA had concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds. Based on comparison to analogous perfluorinated chemicals, EPA had identified concerns for lung effects. Based on submitted test data, EPA had also identified concerns for systemic effects for P–06–206. Based on potential persistent perfluorinated degradation products and submitted data for P–06–206, EPA predicted concern for possible environmental effects. The Order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. The Order was also issued under TSCA section 5(e)(1)(A)(ii)(II), based on a finding that the substances are or will be produced in substantial quantities and that the substances either enter or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substances. To protect against these risks, the Order required:

• Submit to EPA the results of certain testing described in the Testing section of the Order at least 14 weeks before manufacturing or importing the total confidential volume of all PMNs combined, excluding volumes of the monomer P–06–206, listed in the Order;

• Report annually the impurity content of all confidential impurities and carbon chain length impurities listed in the Order by analyzing representative samples; and

• Establishment of certain hazard communication program requirements.

The proposed SNUR would designate as a ''significant new use'' the absence of the second and third of these protective measures. Additionally, the proposed SNUR would designate the following as significant new uses:

• Use other than as textile treatment additives (P–05–491, P–05–492, P–05–505, P–05–838, P–06–207, P–06–208, P–06–211, P–06–215, P–06–217, and P–06–224), carpet treatment additives (P–05–503, P–06–213, and P–06–216), a tile surface treatment (P–05–504), a monomer for textile treatment additives (P–06–206), a nonwoven internal additive (P–06–212), or a paper treatment additive (P–06–214); and

• Manufacture beyond an annual production volume of 2500 lbs.

Potentially Useful Information: EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic human health toxicity, physical/chemical properties, fate, transport, and chronic ecotoxicity testing performed on the PMN substances may be potentially useful to characterize the health and environmental effects of the PMN substances. Manufacturers or processors considering submitting a SNUN and/or developing this information should also know that the PMN submitter agreed not to exceed the time limit specified in the Order without performing the required testing outlined in the Testing section of the Order.

VI. Applicability of the Proposed Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the proposed significant new uses are not ongoing.

For chemical substances identified in this proposed rule that have been added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA Orders have been issued for these chemical substances, and the PMN submitters are prohibited by the TSCA Orders from undertaking activities which would be designated as significant new uses. The identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85. In addition, for other significant new uses EPA has identified in this proposed rule that are not related to Order

requirements, EPA reviewed CDR reporting for those chemicals as described in Unit IV and determined that the uses were either not ongoing or were unlikely to be ongoing. Based on this, the Agency proposes to conclude that none of the significant new uses described in the regulatory text of this proposed rule are ongoing. EPA solicits comment on whether any of the uses that would be regulated as a ''significant new use'' if this proposed rule is finalized are ongoing.

EPA designates December 2, 2022 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the chemical substances for a significant new use after the date this proposal publishes in the **Federal Register**, that person would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *https://www.epa.gov/tsca-inventory.*

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known or reasonably ascertainable (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit V. lists potentially useful information for the SNURs listed in this document. Descriptions of this information is provided for informational purposes. The potentially useful information identified in Unit V. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages dialog with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce.*

The potentially useful information listed in Unit V. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental releases that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40. E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket for this rulemaking.

X. Statutory and Executive Order Reviews

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

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

This action proposes to establish SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

The information collection activities associated with SNURs have already been approved by OMB under the PRA and assigned OMB control number 2070–0012 (EPA ICR No. 574). This proposed rule does not contain any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing

respondent burden, including using automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was 10 in Federal fiscal year (FY) FY2016, 14 in FY2017, 16 in FY2018, five in FY2019, seven in FY2020, and 13 in FY2021, and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $19,020 to $3,330. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,094 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on States, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

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

This action would not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes. This action would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect 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 this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use, and because this action is not expected to affect energy supply, distribution, or use and because this action has not otherwise been designated as a significant energy action by the Administrator of OMB's Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

J. Executive Orders 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and 14008: Tackling the Climate Crisis at Home and Abroad

EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 721

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

Dated: November 28, 2022.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11716 through 721.11751 to subpart E to read as follows:

Subpart E–Significant New Uses for Specific Chemical Substances

Sec.

* * * * *

721.11716 Fluoroacrylate copolymer (generic).

721.11717 Perfluoroalkylsulfonamidoalkyl acrylate, polymer with acrylic acid derivatives (generic).

721.11718 Urethane polymer modified with perfluoroalkylsulfonamide (generic).

721.11719 Urethane polymer modified with perfluoroalkylsulfonamide and polyethoxylate (generic).

721.11720 Urethane polymer modified with perfluoroalkylsulfonamide (generic).

721.11721 Copolymer of perfluoroalkylsulfonamidoalkyl acrylate and alkyl acrylate modified fatty acid dimers (generic).

721.11722 Phosphonium, triphenyl(phenylmethyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

721.11723 Alkane carboxylic acids esters with long chain fatty alcohol and fluorinated alkylsulfonamidoalkyl alcohol (generic).

721.11724 Blocked fluorochemical urethane (generic).
721.11725 Polyperfluoro alkylene glycol, perfluoroalkoxy- and hydroxy alkyl amido perfluoroalkyl terminated (generic).
721.11726 Fluoroalkene substituted alkene polymer (generic).
721.11727 Phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).
721.11728 Fluoroacrylate modified urethane (generic).
721.11729 Fluorinated oligomer alcohol (generic).
721.11731 Perfluoroalkylethyl methacrylate copolymer (generic).
721.11732 Perfluoroalkylethyl methacrylate copolymer organic acid salt (generic).
721.11733 Ethylene-tetrafluoroethylene-fluorinated alkene copolymer (generic).
721.11734 Fluorochemical ester (generic).
721.11735 Fluoroalkylacrylate copolymer (generic).
721.11736 Fluoroalkylacrylate copolymer (generic).
721.11737 Fluorochemical urethane (generic).
721.11738 Fluoroalkylacrylate copolymer (generic).
721.11739 Fluoroalkylacrylate copolymer (generic).
721.11740 Fluoroalkylacrylate copolymer (generic).
721.11741 Fluoroalkyl acrylate (generic).
721.11742 Fluoroalkylacrylate copolymer (generic).
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721.11746 Fluoroalkylacrylate copolymer (generic).
721.11747 Fluoroalkylacrylate copolymer (generic).
721.11748 Fluoroalkylacrylate copolymer (generic).
721.11749 Fluoroalkylacrylate copolymer (generic).
721.11750 Fluoroalkylacrylate copolymer (generic).
721.11751 Fluoroalkylacrylate copolymer (generic).

§ 721.11716 Fluoroacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as a fluoroacrylate copolymer (PMN P–00–1085; Accession No. 249720) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a surfactant in paint and coatings manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11717 Perfluoroalkyl sulfonamidoalkyl acrylate, polymer with acrylic acid derivatives (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoroalkylsulfonamidoalkyl acrylate, polymer with acrylic acid derivatives (PMN P–01–584; Accession No. 254456) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a surfactant in adhesive and synthetic rubber manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11718 Urethane polymer modified with perfluoroalkylsulfonamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as urethane polymer modified with perfluoroalkylsulfonamide (PMN P–02–16; Accession No. 252290) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is

any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11719 Urethane polymer modified with perfluoroalkylsulfonamide and polyethoxylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as urethane polymer modified with perfluoroalkylsulfonamide and polyethoxylate (PMN P–02–195; Accession No. 271739) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication:* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11720 Urethane polymer modified with perfluoroalkylsulfonamide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as urethane polymer modified with perfluoroalkylsulfonamide (PMN P–02–609; Accession No. 279755) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as an anti-stain agent.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11721 Copolymer of perfluoroalkylsulfonamidoalkyl acrylate and alkyl acrylate modified fatty acid dimers (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as copolymer of perfluoroalkylsulfonamidoalkyl acrylate and alkyl acrylate modified fatty acid

dimers (PMN P–02–700; Accession No. 259360) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11722 Phosphonium, triphenyl(phenylmethyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as phosphonium, triphenyl(phenylmethyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1) (PMN P–02–891; CAS No. 332350–93–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=1.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11723 Alkane carboxylic acids esters with long chain fatty alcohol and fluorinated alkylsulfonamidoalkyl alcohol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkane carboxylic acids esters with long chain fatty alcohol and fluorinated alkylsulfonamidoalkyl alcohol (PMN P–02–920; Accession No. 257922) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as an additive. It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), a (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11724 Blocked fluorochemical urethane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as blocked fluorochemical urethane (PMN P–03–32; Accession No. 242467) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a protective treatment. It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11725 Polyperfluoro alkylene glycol, perfluoroalkoxy- and hydroxy alkyl amido perfluoroalkyl terminated (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyperfluoro alkylene glycol, perfluoroalkoxy- and hydroxy alkyl amido perfluoroalkyl terminated (PMN P–03–33; Accession No. 242467) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g). It is a significant new use to manufacture the substance with an average molecular weight less than 1000 daltons, more than 5 percent oligomeric material less than 500 daltons, or more than 10 percent oligomeric material less than 1000 daltons. It is a significant new use to manufacture the substance without analyzing the molecular weight of the substance produced at each facility as described in the TSCA 5(e) order for the substance. It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11726 Fluoroalkene substituted alkene polymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkene substituted alkene polymer (PMN P–03–67) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance

other than primarily as an alternating copolymer made up of the confidential monomers specified in the Order to prevent creation of long-chain perfluorinated acids including PFOA. It is a significant new use to manufacture or import the substance without analyzing representative samples of the substance or measuring initial concentrations of reactants consistent with the procedure specified in the TSCA Order. It is a significant new use to use the substance other than as a paint additive. It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11727 Phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Phosphonium, tributyl (2-methoxypropyl)-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-1-butanesulfonamide (1:1) (PMN P–03–77; CAS No. 332350–93–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a cure catalyst or a chemical intermediate.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11728 Fluoroacrylate modified urethane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroacrylate modified urethane (PMN P–04–174; Accession No. 238427) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a protective coating.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11729 Fluorinated oligomer alcohol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluorinated oligomer alcohol (PMN P–04–176; Accession No. 236181) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used

in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11731 Perfluoroalkylethyl methacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer (PMN P–05–75; Accession No. 245831) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11732 Perfluoroalkylethyl methacrylate copolymer organic acid salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer organic acid salt (PMN P–05–107: Accession No. 257171) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11733 Ethylene-tetrafluoroethylene-fluorinated alkene copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as ethylene-tetrafluoroethylene-fluorinated alkene copolymer (PMN P–04–289; Accession No. 258981) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not

being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance other than according to the confidential synthesis and composition requirements in the Order. It is a significant new use to use the substance other than as a copolymer for automotive and industrial parts. It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11734 Fluorochemical ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluorochemical ester (PMN P–04–537; Accession No. 264949) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a finishing agent in textiles, apparel, and leather manufacturing or as a chemical intermediate.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11735 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–05–491) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11736 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–05–492) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication:* A significant new use of the substance is any manner or method of manufacture,

import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11737 Fluorochemical urethane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluorochemical urethane (PMN P–05–503) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a carpet treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11738 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–05–504) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a tile surface treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11739 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–05–505) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11740 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–05–838) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11741 Fluoroalkyl acrylate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkyl acrylate (PMN P–06–206) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have

received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a monomer for textile treatment additives. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11742 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–207) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11743 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–208) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11744 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–211) is subject to reporting under this section for the

significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11745 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–212) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a nonwoven internal additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11746 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–213) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a carpet treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis

and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11747 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–214) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a paper treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11748 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–215) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11749 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–216) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information

to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a carpet treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11750 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–217) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

§ 721.11751 Fluoroalkylacrylate copolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluoroalkylacrylate copolymer (PMN P–06–224) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Hazard communication.* A significant new use of the substance is any manner or method of manufacture, import, or processing associated with any use of the substance without the following hazard communication: (A) If the employer becomes aware of any significant new information regarding hazards of the substance or ways to protect against the hazards, the employer must incorporate this new information and any information on methods for protecting against such hazards, into an SDS as described in § 721.72(c) within 90 days from the time the employer becomes aware of the new information. If the substance is not being manufactured, processed, or used in the employer's workplace, the employer must add the new information to an SDS before the substance is reintroduced into the workplace.

(B) The employer must ensure that persons who will receive the substance from the employer, or who have received the substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an SDS containing the information required under paragraph (a)(2)(i)(A) of this section within 90 days from the time the employer becomes aware of the new information.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the substance beyond an annual production volume of 2500 lbs. It is a significant new use to use the substance other than as a textile treatment additive. It is a significant new use to manufacture the substance without the analysis, reporting of the analysis to EPA, and minimizing of the impurity content of all confidential impurities and carbon chain lengths as described in the Chemical Synthesis and Composition section of the TSCA section 5(e) Order for the substance.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Exemptions.* The exemption of § 721.45(i) does not apply to this section.

[FR Doc. 2022–26252 Filed 12–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS–9898–NC]

RIN 0938–AV14

Request for Information; Essential Health Benefits

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

ACTION: Request for information.

SUMMARY: This request for information (RFI) solicits public comment on issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (the Affordable Care Act or ACA). CMS is issuing this RFI to gather input from the public regarding a variety of topics related to the coverage of benefits in health plans subject to the EHB requirements of the ACA. These topics include: the description of the EHB, the scope of benefits covered in typical employer plans, the review of EHB, coverage of prescription drugs, and substitution of EHB.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by January 31, 2023.

ADDRESSES: In commenting, refer to file code CMS–9898–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9898–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9898–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Leigha Basini, (301) 492–4380, or Rebecca Bucchieri, (301) 492–4341, for general information.

Ken Buerger, (410) 786–1190.

Nathan Caulk, (667) 290–9975.

Nicole Levesque, (667) 290–9974.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Section 1301(a)(1)(B) of the Affordable Care Act [1] requires all issuers of qualified health plans (QHPs) to cover the ''Essential Health Benefits (EHB) package'' described in section 1302(a) of the ACA, which includes coverage of the services described in section 1302(b) of the ACA. Section 2707(a) of the Public Health Service Act (PHS Act) extends the requirement to cover the ''EHB package'' to non-grandfathered individual and small group health insurance coverage (hereinafter, such plans are referred to as plans subject to EHB requirements), irrespective of whether such coverage is offered through an Exchange.

Section 1302 of the ACA provides for the establishment of this ''EHB package'' to include coverage of the EHB (as defined by the Secretary), cost-sharing limits, and actuarial value (AV) requirements. Section 1302(b) of the ACA directs the Secretary, in defining the EHB, to ensure that they are equal in scope to the benefits provided under a typical employer plan, and that they include at least the following 10 general categories and the items and services covered within the categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

On December 16, 2011, HHS released a bulletin [2] that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). As implemented in the EHB Rule, for a non-grandfathered individual or small group market health plan to provide the ''EHB package,'' the health plan must, among other things, provide the benefits in accordance with the State's EHB-benchmark plan, as described at 45 CFR 156.115. A State's EHB-benchmark plan serves as a reference plan for the benefits considered as EHB in the State. Section 156.115(a) states that the provision of EHB means that a health plan, among other things, provides benefits that are substantially equal to the State's EHB-benchmark plan including: covered benefits; limitations on coverage including coverage of benefit amount, duration, and scope; and prescription drug benefits that meet the requirements of § 156.122.[3]

For plan years 2014 through 2016, each State's EHB-benchmark plan was based on one of the health plans identified at § 156.100 that was available in the State in 2012, with any missing benefit categories supplemented as specified under § 156.110.[4] For plan

[1] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this request for information, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act'' or ''ACA''.

[2] The HHS EHB bulletin is available on the CMS website at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[3] An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan pursuant to § 156.115(b).

[4] As specified by § 156.100(c), for plan years beginning prior to January 1, 2020, if a State did not

Continued

years 2017, 2018, and 2019, each State's EHB-benchmark plan was based on one of the health plans identified at § 156.100 that was available in the State in 2014, with any missing benefit categories supplemented as specified under § 156.110.

The 2019 Payment Notice final rule, which appeared in the April 17, 2018 **Federal Register** (83 FR 16930), added § 156.111 to provide States with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond. In that final rule, we stated that we believe States should have additional choices with respect to benefits and affordable coverage, and we added § 156.111 to provide additional flexibility for States to select new EHB-benchmark plans starting with the 2020 plan year.[5] To date, CMS has approved changes to 7 State EHB-benchmark plans under § 156.111.[6] For each plan year, States that opt not to exercise this flexibility use the same EHB-benchmark plan from the previous plan year. The current EHB-benchmark plans are available on the CMS website at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.*

II. Solicitation of Public Comments

CMS requests comments from all interested parties to gain a better understanding of the coverage of benefits in health plans with respect to the following specific areas:

Benefit Descriptions in EHB-Benchmark Plan Documents

The EHB-benchmark plan approach was designed to ''allow States to build on coverage that is already widely available, minimize market disruption, and provide consumers with familiar products. This should heighten consumer understanding of plan options and may facilitate consumers' abilities to make choices that better suit their needs.'' [7] We believe that this approach was largely successful in these regards. At the same time, we are mindful of concerns that this approach creates a patchwork of coverage of EHB, such that any particular benefit may have disparate coverage nationwide across all 51 EHB-benchmark plans.

We are also mindful that the EHB-benchmark plan documents can describe the covered benefits differently, which may create ambiguity in defining the EHB in a particular State. For example, one State's EHB-benchmark plan may specifically mention coverage of ground, water, and air ambulance, while another State's EHB-benchmark plan may simply cover ''medically necessary transportation'' without distinguishing whether such coverage includes ground, water, or air ambulance. As another example, one EHB-benchmark plan may cover ''Diagnostic radiology services and Imaging studies,'' while another EHB-benchmark plan has a more detailed description of covered radiological and imaging benefits: ''Benefits are also available for advanced imaging services, which include but are not limited to: CT scan, CTA scan, Magnetic Resonance Imaging (MRI), Magnetic Resonance Angiography (MRA), Magnetic resonance spectroscopy (MRS), Nuclear Cardiology, PET scans, PET/CT Fusion scans, QTC Bone Densitometry, Diagnostic CT Colonography.'' Accordingly, some State EHB-benchmark plan documents are well over 100 pages and include these more detailed descriptions of covered benefits and limitations, while other EHB-benchmark plans are only a few dozen pages with shorter, more generalized descriptions of covered benefits and limitations.

The difference in how the benefits are described in the EHB-benchmark plans is not particularly surprising. These plan documents were written by different authors at different times, serving different segments of the population with different health needs, and subjected to different Federal or State requirements. We understand that the authors of the plan documents used as the EHB-benchmark plans may not have anticipated that the language used in that plan document would be used to define the EHB for a State indefinitely. Even now, with States able to change their EHB-benchmark plan by selecting a set of benefits to become the State's EHB-benchmark plan under § 156.111(a)(3), we believe it may be unreasonable to expect a State to exhaustively describe all covered benefits and limitations in their EHB-benchmark plan document.

Based on our experience and review of the EHB-benchmark plan documents, it is apparent that the more descriptive an EHB-benchmark plan document is, the greater the certainty is that a specific benefit is considered to be an EHB in the State. As a result, it is difficult for States, CMS, and other interested parties to reliably compare the EHB-benchmark plan document from one State to another. This inhibits State and Federal ability to gauge the overall generosity of plans subject to EHB requirements, which makes it more difficult for States to consider changes to their EHB-benchmark plans under § 156.111(a)(1) and (2).[8] It also makes it more difficult for CMS to fulfill its statutory obligation at section 1302(b)(4)(G) and (H) of the ACA to periodically review and update the EHB to address gaps in coverage or changes in evidence basis.

To be clear, we do not necessarily believe that this ambiguity in the covered benefits and limitations in the EHB-benchmark plans has resulted in overt consumer harm. For example, based on our discussions with States and a lack of consumer complaints about exclusions or claims denials, plans subject to EHB requirements do not appear to be excluding services that are generally understood to be covered, regardless of their specific inclusion in the relevant EHB-benchmark plan document. Accordingly, we believe that the States have generally proven to be effective enforcers of the EHB requirement in ensuring that benefits are still treated as EHB in instances where the EHB-benchmark plan language is ambiguous or lacking in detail.[9] We seek public comment on this understanding, including to what extent States may require additional guidance on how to ensure that plans are interpreting the EHB-benchmark plan documents in a manner that provides EHB coverage to consumers, consistent with applicable requirements.

Typical Employer Plans

Section 1302(b)(2)(A) of the ACA requires the scope of the EHB to be equal to the scope of benefits provided under a ''typical employer plan.'' To implement section 1302(b) of the ACA and the typical employer plan standard, CMS defined EHB based on a

make an EHB-benchmark selection using the process described in the section, the State's EHB-benchmark defaulted to the largest plan by enrollment in the largest product by enrollment in the State's small group market.

[5] Under § 156.111(a), a State may change its EHB-benchmark plan by: (1) selecting the EHB-benchmark plan that another State used for the 2017 plan year; (2) replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same category or categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year; or (3) otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

[6] Illinois (2020), South Dakota (2021), Michigan (2022), New Mexico (2022), Oregon (2022), Colorado (2023), and Vermont (2024).

[7] 78 FR 12833, 12860 (February 25, 2013).

[8] In addition, it inhibits the ability of self-insured plans to gauge the overall scope of items and services included in EHB-benchmark plans for purposes of selecting a definition of EHB to comply with the requirement to limit enrollee cost sharing to the annual limitation on cost sharing and the prohibition of lifetime or annual limits. See 45 CFR 147.126(c) and ACA Implementation FAQ 18 at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.*

[9] CMS has the responsibility to directly enforce the relevant Public Health Service Act provisions with respect to health insurance issuers in the group and individual markets in Missouri, Oklahoma, Texas, and Wyoming.

benchmark plan approach at § 156.100(a). States were required to select from one of 10 base-benchmark plans, including the largest health plan by enrollment in any of the three largest small group insurance products by enrollment, any of the largest three State employee health benefit plan options by enrollment and generally available to State employees in the State involved, any of the largest three national Federal Employees Health Benefits (FEHB) Program plan options by aggregate enrollment that are offered to all FEHB-eligible Federal employees, or the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

In the 2019 Payment Notice, we finalized options at § 156.111 to provide States with greater flexibility to select new EHB-benchmark plans beginning with the 2020 plan year, if they so choose. A State's EHB-benchmark plan must still provide a scope of benefits equal to the scope of benefits provided under a typical employer plan.[10] For plan year 2020 and after, § 156.111(b)(2) defines a typical employer plan as either (1) one of the selecting State's 10 base-benchmark plan options established at § 156.100 from which the State was able to select for the 2017 plan year; or (2) the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting State, provided that the plan meets the requirements in § 156.111(b)(2)(i)(B)(*1*) through (*4*).

We seek comment on changes in the scope of benefits offered by employer plans since plan year 2014. In particular, we are interested in comments that discuss the relative generosity of the current typical employer plans described at § 156.100(a)(1) through (4) and § 156.111(b)(2)(i)(B), and whether they are reflective of the scope of benefits provided under employer plans offered in more recent plan years, or whether employer plans offered since plan year 2014 are more or less generous. We seek comment on whether there are other employer plans commonly sold in States that are not reflected in the current typical employer plans described at § 156.100(a)(1) through (4) and § 156.111(b)(2)(i)(B). We invite our State partners to elaborate on whether changes in State markets since 2014 may warrant changes to the current definition of a ''typical employer plan.''

Review of EHB

Section 1302(b)(4)(G)(i) through (iv) of the ACA require CMS to periodically review the EHB to determine: (1) whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost; (2) whether EHB need to be modified or updated to account for changes in medical evidence or scientific advancement; (3) information on how EHB will be modified to address any such gaps in access or changes in the evidence base; and (4) the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations. In furtherance of this statutory obligation, we seek comment on each of these topics.

Barriers of Accessing Services Due to Coverage or Cost

First, we seek comment on whether and to what extent consumers enrolled in plans that provide EHB are facing any difficulty accessing needed services due to coverage or cost. Specifically:

- Are there significant barriers for consumers to access mental health and substance use disorder services, including behavioral health services that are EHB? To what extent has the utilization of telehealth impacted access to the behavioral health services that are EHB, particularly during the COVID–19 pandemic? How could telehealth utilization better address potential gaps in consumer access to EHB for behavioral health services or other health care services?
- What other strategies have plans implemented to broaden access to telehealth services?
- What efforts have plans found effective in controlling costs of EHB? To what extent do plans that provide EHB see increased utilization and higher costs if those efforts are not implemented? What strategies have consumers and providers seen plans implement to reduce utilization and costs, such as use of prior authorization, step therapy, etc.? Are these strategies to reduce utilization and costs applied broadly or are they targeted to a specific area? What, if any, geographic differences have been found in the strategies plans use to reduce utilization and costs within a State? How are these tools effective or ineffective? To what extent do these tools curb or complicate access to medically necessary care?

Changes in Medical Evidence and Scientific Advancement

Second, we seek comment on whether and to what extent the EHB need to be modified or updated to account for changes in medical evidence and scientific advancement. We expect that there have been significant changes in medical evidence and scientific advancement for certain benefits since 2014. For example, after the original EHB-benchmark plans had been selected, silver diamine fluoride, which is an inexpensive treatment that can stop dental caries and is particularly useful for pediatric populations, became available in the U.S.[11] Another example of a change in medical evidence is the increased understanding of and reliance on doula services as a cost-effective way to improve maternal and newborn health outcomes.[12] To that end:

- What changes in medical evidence and scientific advancement have occurred since 2014 that are not reflected in the current EHB-benchmark plans? Are there benefits widely covered as EHB that are not supported by current medical evidence?
- Are there other barriers to incorporating changes in medical evidence and scientific advancement into the EHB? How can the EHB better track with changes in medical evidence and scientific advancement? What steps should be taken to address EHB that are not supported by current medical evidence?

We are also interested in how changes in medical evidence or scientific advancement generally could inform CMS' health equity and nondiscrimination efforts with regards to EHB. For example, there may be lack of coverage for treatment informed by scientific advancements in certain areas of health care resulting in a disproportionate impact on consumers, or there may be new medical evidence indicating certain consumers are encountering specific barriers in accessing certain EHB. To that end:

- How might the EHB adapt to more quickly address pressing public health issues such as public health emergencies (including the opioid and overdose epidemic) and maternal

[10] Or greater than the scope of benefits provided under a typical employer plan to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a).

[11] Crystal YO, Niederman R. Evidence-Based Dentistry Update on Silver Diamine Fluoride. Dent Clin North Am. 2019 Jan;63(1):45–68. doi: 10.1016/j.cden.2018.08.011. PMID: 30447792; PMCID: PMC6500430. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500430/*.

[12] Greiner KS (et al.). The Cost-Effectiveness of Professional Doula Care for a Woman's First Two Births: A Decision Analysis Model. Journal of Midwifery & Women's Health. Available at *https://onlinelibrary.wiley.com/doi/full/10.1111/jmwh.12972*.

mortality rates (particularly among underserved populations)? For example, what are the barriers for third-parties such as family members or caregivers to obtain naloxone?

- How should the EHB advance health equity by taking into consideration economic, social, racial, or ethnic factors that are relevant to health care access (for example, access to appropriate language services)?
- In what ways could EHB better address health conditions that disproportionately affect underserved populations or large parts of the American population?
- For example, how could EHB address nutrition-related health conditions for the American population? How has the medical evidence regarding nutrition-related health conditions changed since 2014? How can EHB better improve nutrition-related health outcomes for the populations that are most likely to benefit from coverage of nutrition-related care, such as people with diabetes?
- What strategies are issuers and plan sponsors using to improve nutritional-related health outcomes for enrollees, and what strategies could they implement? To what extent have issuers and plan sponsors designed their own strategies as compared to relying on existing models (for example, the evidence-based National Diabetes Prevention Program [13])?
- How have scientific advancements and new delivery mechanisms impacted the content of nutrition-related care, provider delivery, access to care, and how plan sponsors and issuers manage it?

Addressing Gaps in Coverage

Third, we seek comment on how the EHB could be modified to address any gaps in coverage or scope of benefits. Specifically:

- Are there examples of benefits that are essential to maintaining health, including behavioral health, that are insufficiently covered as EHB but that are routinely covered by other specific health plans or programs, such as employer-sponsored plans, Medicare, and Medicaid? To what extent does the EHB cover screening, consultative, and treatment modalities that supports the integration of both mental health and substance use disorder services into primary care?
- Many State base-benchmark plan documents do not include specific coverage for habilitative services. To comply with section 1302(b)(1)(G) of the ACA, these States supplement the base-benchmark plans with habilitative services pursuant to § 156.110(f) by determining which services in that category will be covered as EHB.[14] In our experience, State supplementation of habilitative services is inconsistent. We are interested in comments on which habilitative services are currently covered as EHB, and whether further definition is needed in general to clarify the covered benefits. We also seek comment on whether EHB-benchmark plans' current coverage and limits regarding habilitative services, which were primarily based on coverage for rehabilitative purposes, are sufficient and in line with current clinical guidelines for treatment of developmental disabilities.
- Is there sufficient coverage as EHB of emergency behavioral health services, including mobile crisis care and stabilization services? To what extent is there sufficient coverage as EHB for other levels of care, such as for crisis prevention and care coordination for behavioral health services? To what extent do plans that provide EHB include peer and recovery support for behavioral health services?
- Aside from the required preventive services for children,[15] and the identification in section 1302(b)(1)(J) of the ACA for ''[p]ediatric services, including oral and vision care'' as one of the 10 categories of EHB, the EHB-benchmark plans largely do not differentiate between benefits for adults and benefits for children. Are there differences between adult and pediatric benefits and those populations' needs such that further delineation of pediatric benefits is warranted? How does the scope of health benefits for children compare between employer-sponsored group health plans and States' separate Children's Health Insurance Program plans?
- To what extent could EHB better address any gaps in coverage for those with chronic and lifelong conditions?
- How can CMS balance State flexibility (as States are generally the primary enforcers of EHB) with the statutory requirement to ensure sufficient coverage for a diverse population, including those living in rural areas who may have limited provider types available?
- What other strategies could be implemented to modify EHB to address gaps in coverage or changes in the evidence base?

Actuarial and Cost-Sharing Limitations

Lastly, we recognize that any efforts to revise the EHB to change the benefits covered as EHB have the potential to impact costs and the ability of plans to meet the actuarial and cost-sharing limitations under section 1302 of the ACA. We invite comments that address the ability of plans subject to EHB requirements to conform benefit designs to these requirements.

Coverage of Prescription Drugs as EHB

As finalized in the EHB Rule, plans subject to EHB requirements must comply with § 156.122(a)(1) to cover at least the same number of prescription drugs in every United States Pharmacopeia (USP) category and class as covered by the State's EHB-benchmark plan, or one drug in every category and class, whichever is greater. We also stated that plans could exceed the minimum number of drugs required to be covered and that additional drugs would still be considered EHB. In that final rule,[16] we chose to use the USP Model Guidelines Version 5.0 (USP Guidelines) to classify the drugs required to be covered as EHB under § 156.122(a)(1). In so doing, we noted that ''[w]hile there was concern among commenters on the use of USP as the system, there was no universal system identified as a potential alternative. We chose the current version USP Model Guidelines (version 5) because it is publicly available and many pharmacy benefit managers are familiar with it. We believe the USP model best fits the needs for the years 2014 and 2015 during the transitional EHB policy.'' [17] CMS and the USP developed the USP Guidelines in 2004 to implement the Medicare Part D Prescription Drug Program.[18] Section 1860D–2(e) of the Social Security Act (the Act) defines a ''covered part D drug'' for purposes of the Medicare Part D program, and the statutory definition excludes certain drugs,[19] such as drugs for anorexia, weight loss, or weight gain.[20]

[13] National Diabetes Prevention Program. Available at *https://www.cdc.gov/diabetes/prevention/index.html.*

[14] 45 CFR 156.110(f) states: ''If the base-benchmark plan does not include coverage for habilitative services, the State may determine which services are included in that category.''

[15] See generally 45 CFR 147.130(a)(1).

[16] 78 FR at 12846.

[17] 78 FR at 12845–12846.

[18] USP Medicare Model Guidelines. Available at *https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines.*

[19] See section 1860D–2(e)(2) of the Act.

[20] See section 1927(d)(2) of the Act. List of Drugs Subject to Restriction include drugs used for anorexia, weight loss, weight gain, fertility, cosmetic purposes or hair growth, symptomatic relief of cough and colds, smoking cessation, prescription vitamins and mineral products, nonprescription drugs, certain covered outpatient drugs, barbiturates, benzodiazepines, and drugs for the treatment of sexual or erectile disfunction.

Consequently, the USP Guidelines do not include categories and classes to classify these excluded drugs; as a result, these drugs are not required to be covered as EHB under § 156.122(a)(1). However, certain types of weight management drugs may still be covered in a health plan as EHB but under a different drug category (for example, weight management drugs classified and covered under the category for central nervous system drugs). Additionally, nothing prevents plans from voluntarily covering these drugs as EHB. However, the variation in classification for these drugs leads to potential coverage gaps for consumers.

In the 2016 Payment Notice,[21] we solicited comments regarding whether to replace the USP Guidelines with a standard based on the American Hospital Formulary Service (AHFS) or another drug classification system. CMS ultimately decided to retain the USP Guidelines classification system because ''[i]ssuers have already developed 2 years of formularies based on it, States have already developed systems to review those formularies, and interested parties are familiar with the system. Thus, while AHFS had the benefit of being updated more frequently and incorporating a broader set of classes and subclasses, commenters did not uniformly support its use because of several issues, including a lack of transparency, the need to supplement certain classes when compared with USP, and the complexity of the AHFS system.'' [22]

In 2017, the USP developed a second drug classification system, the USP Drug Classification (DC), an independent drug classification system ''developed in response to input from interested parties that it would be helpful to have a classification system beyond the Medicare Model Guidelines (MMG) to assist with formulary support outside of Medicare Part D.'' [23] We note that USP DC system has many features that may be beneficial to consumers and meet evolving public health challenges. The USP DC system provides examples of common U.S. outpatient drugs and is updated annually.

We recognize the potential challenges of switching drug classification systems for EHB. We reviewed public comments for the proposed 2016 Payment Notice related to the AHFS system and recognize the concerns of lack of transparency or the need to supplement certain classes when compared with USP Guidelines, and the complexity of the AHFS system. However, we note that other drug classification systems, such as USP DC or others, may provide greater benefit for consumers. In addition, we note that switching to the USP DC system may not be as disruptive as switching to AHFS due to the unique features of the USP DC system such as applicability and readiness of the system. We seek public comment to confirm or further expand on our understanding of the risks and benefits of replacing the current USP Guidelines with a different drug classification system.

We seek comment on whether CMS should consider using an alternative prescription drug classification standard for defining the EHB prescription drug category, such as the USP DC or others, in the future.

Substitution of EHB

In the EHB Rule, we added § 156.115(b) so that health plans may substitute benefits for those provided in the EHB-benchmark plan, provided that the substitution is actuarially equivalent and the benefit is not a prescription drug benefit. We added this flexibility ''to provide greater choice to consumers, and promote plan innovation through coverage and design options.'' [24] In the 2019 Payment Notice, we modified paragraph (b)(1)(ii) to allow States to permit issuers to substitute benefits within the same EHB category *and* between EHB categories, as long as the substituted benefit is actuarially equivalent to the benefit being replaced and is not a prescription drug benefit.[25] In the 2023 Payment Notice,[26] we amended § 156.115(b)(2) to withdraw the flexibility for health plans to substitute benefits between different EHB categories in response to public comments that the practice could lead to adverse selection and discrimination by allowing health plans to remove benefits needed by people with significant health needs and substitute them with benefits meant to attract healthier enrollees.

Ever since we implemented the ability for the substitution of EHB, we have received substantial feedback urging CMS to remove the ability for health plans to substitute EHB because of concerns that the practice could lead to discrimination or negative health outcomes. Others have expressed concerns that allowing such substitution makes it difficult for regulators to ensure that plans are actually covering the EHB and that substitution could be confusing for consumers. However, we have also received feedback that the option of substitution may allow plans flexibility in benefit design to address changing public health concerns and cover innovations in health care as EHB.

To date, CMS has not received any information that any health plan has ever substituted an EHB using this flexibility. While States are not required to notify CMS when health plans substitute benefits under § 156.115(b), any health plan seeking certification as a QHP on a Federally-facilitated Exchange (FFE) may indicate, at its option, whether a particular benefit is substituted in its QHP application. CMS, as operator of the FFEs, has not received any QHP application that indicates that any QHP issuer on an FFE has substituted a benefit in this manner. We seek comment regarding the extent to which health plans have ever substituted EHB under § 156.115.

To the extent the substitution of EHB is not widely used by health plans, we seek comment on how we might revisit our rules regarding the substitution of EHB in future rulemaking so that consumers have access to health plans that can better address changing public health concerns or innovation in health care. Alternatively, we seek comment regarding whether health plans should not be permitted to substitute EHB within the same EHB category.

III. Collection of Information Requirements

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does

[21] 2016 Final Payment Notice: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10750, 10813 (February 27, 2015). Available at *https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.*

[22] *Id.*

[23] USP Drug Classification. Available at *https://www.usp.org/health-quality-safety/usp-drug-classification-system.*

[24] 78 FR 12833, 12844 (February 25, 2013).

[25] 83 FR 16930, 16930 (April 17, 2018).

[26] 87 FR 27208 (May 6, 2022).

not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. CMS notes that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, CMS will not respond to questions about the policy issues raised in this RFI.

CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. These communications would be for the sole purpose of clarifying Statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Responders should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, CMS may publicly post the public comments received, or a summary of those public comments.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 14, 2022.

Dated: November 29, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–26282 Filed 11–30–22; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 4

[PS Docket No. 21–346, 15–80 and ET Docket 04–35; Report No. 3188; FR ID 115942]

Petition for Clarification and Partial Reconsideration

AGENCY: Federal Communications Commission.

ACTION: Petition for Clarification and Partial Reconsideration.

SUMMARY: Petition for Clarification and Partial Reconsideration (Petition) has been filed in the Commission's proceeding by Thomas C. Power, on behalf of CTIA, et al.

DATES: Oppositions to the Petition must be filed on or before December 19, 2022. Replies to oppositions must be filed on or before December 27, 2022.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Saswat Misra, Public Safety and Homeland Security Bureau, 202–418–0944 or via email at *Saswat.Misra@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3188, released November 17, 2022. The full text of the Petition can be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: Resilient Networks; Amendments to part 4 of the Commission's Rules Concerning Disruptions to Communications; New part 4 of the Commission's Rules Concerning Disruptions to Communications, PS Docket Nos. 21–346, 15–80, ET Docket No. 04–35, Report and Order and Further Notice of Proposed Rulemaking, FCC 22–50 (2022), Report and Order, published at 87 FR 59329, September 30, 2022. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–26294 Filed 12–1–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 221123–0249; RTID 0648–XC347]

Fisheries of the Exclusive Economic Zone Off Alaska; Gulf of Alaska; Proposed 2023 and 2024 Harvest Specifications for Groundfish

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

ACTION: Proposed rule; harvest specifications and request for comments.

SUMMARY: NMFS proposes 2023 and 2024 harvest specifications, apportionments, and Pacific halibut prohibited species catch limits for the groundfish fishery of the Gulf of Alaska (GOA). This action is necessary to establish harvest limits for groundfish during the 2023 and 2024 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska. The 2023 harvest specifications supersede those previously set in the final 2022 and 2023 harvest specifications, and the 2024 harvest specifications will be superseded in early 2024 when the final 2024 and 2025 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the GOA in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Comments must be received by January 3, 2023.

ADDRESSES: Submit comments on this document, identified by NOAA–NMFS–2022–0094, by either of the following methods:

- *Federal e-Rulemaking Portal:* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2022-0094,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments

received are a part of the public record, and NMFS will post the comments for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD) for the Final EIS, and the annual Supplementary Information Reports (SIR) to the Final EIS prepared for this action are available from *https://www.regulations.gov.* An updated 2023 SIR for the final 2023 and 2024 harvest specifications will be available from the same source. The final 2021 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the GOA, dated November 2021, is available from the North Pacific Fishery Management Council (Council) at 1007 West Third, Suite 400, Anchorage, AK 99501–2252, phone 907–271–2809, or from the Council's website at *https://www.npfmc.org.* The 2022 SAFE report for the GOA will be available from the same source.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the GOA groundfish fisheries in the exclusive economic zone (EEZ) of the GOA under the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The Council prepared the FMP under the authority of the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*). Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600, 679, and 680.

The FMP and its implementing regulations require that NMFS, after consultation with the Council, specify the total allowable catch (TAC) for each target species, the sum of which must be within the optimum yield (OY) range of 116,000 to 800,000 metric tons (mt) (§§ 679.20(a)(1)(i)(B) and 679.20(a)(2)). Section 679.20(c)(1) further requires NMFS to publish and solicit public comment on proposed annual TACs and apportionments thereof, Pacific halibut prohibited species catch (PSC) limits, and seasonal allowances of pollock and Pacific cod. The proposed harvest specifications in Tables 1 through 19 of this rule satisfy these requirements. For 2023 and 2024, the sum of the proposed TAC amounts is 443,615 mt.

Under § 679.20(c)(3), NMFS will publish the final 2023 and 2024 harvest specifications after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2022 meeting, (3) considering information presented in the 2023 SIR to the Final EIS that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**), and (4) considering information presented in the final 2022 SAFE report prepared for the 2023 and 2024 groundfish fisheries.

Other Actions Potentially Affecting the 2023 and 2024 Harvest Specifications

Amendment 122 to the Bering Sea and Aleutian Islands FMP: Pacific Cod Cooperative Program

NMFS is developing a proposed rule to implement Amendment 122 to the FMP for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI), which, if approved, would establish the Pacific Cod Trawl Cooperative Program (PCTC Program) to allocate BSAI Pacific cod harvest quota to qualifying groundfish License Limitation Program (LLP) license holders and qualifying processors. The PCTC Program would be a limited access privilege program (LAPP) for the harvest of Pacific cod in the BSAI trawl catcher vessel (CV) sector.

One of the elements of the proposed PCTC Program is to revise the GOA groundfish sideboard limits and halibut PSC limits for LLP licenses that receive allocations of PCTC quota share. The Program would change the American Fisheries Act (AFA) non-exempt GOA groundfish sideboard and halibut PSC limits for all non-exempt AFA LLP licenses and CVs based on the GOA fishing activity of these vessels in the aggregate during the PCTC Program qualifying years. If approved by the Secretary of Commerce, Amendment 122 and its implementing regulations would affect the calculation and establishment of the groundfish sideboard limits discussed in the subsequent section of this rule titled *American Fisheries Act (AFA) Catcher/Processor and Catcher Vessel Groundfish Harvest and PSC Limits.*

Proposed Acceptable Biological Catch (ABC) and TAC Specifications

In October 2022, the Council's Scientific and Statistical Committee (SSC), its Advisory Panel (AP), and the Council reviewed the most recent biological and harvest information about the condition of the GOA groundfish stocks. The Council's GOA Groundfish Plan Team (Plan Team) compiled and presented this information in the final 2021 SAFE report for the GOA groundfish fisheries, dated November 2021 (see **ADDRESSES**). The SAFE report contains a review of the latest scientific analyses and estimates of each species' biomass and other biological parameters, as well as summaries of the available information on the GOA ecosystem and the economic condition of the groundfish fisheries off Alaska. From these data and analyses, the Plan Team recommends, and the SSC sets, an Overfishing Limit (OFL) and Acceptable Biological Catch (ABC) for each species and species group. The amounts proposed for the 2023 and 2024 OFLs and ABCs are based on the 2021 SAFE report. The AP and Council recommended that the proposed 2023 and 2024 TACs be set equal to proposed ABCs for all species and species groups, with the exception of the species and species groups further discussed below. The proposed OFLs, ABCs, and TACs could be changed in the final harvest specifications depending on the most recent scientific information contained in the final 2022 SAFE report. The individual stock assessments that will comprise, in part, the 2022 SAFE report are available at *https://www.fisheries.noaa.gov/alaska/population-assessments/north-pacific-groundfish-stock-assessment-and-fishery-evaluation.* The final 2022 SAFE report will be available from the same source.

In November 2022, the Plan Team will update the 2021 SAFE report to include new information collected during 2022, such as NMFS stock surveys, revised stock assessments, and catch data. The Plan Team will compile this information and present the draft 2022 SAFE report at the December 2022 Council meeting. At that meeting, the SSC and the Council will review the 2022 SAFE report, and the Council will approve the 2022 SAFE report. The Council will consider information in the 2022 SAFE report, recommendations from the November 2022 Plan Team meeting and December 2022 SSC and AP meetings, public testimony, and relevant written public comments in making its recommendations for the final 2023 and 2024 harvest specifications. Pursuant to § 679.20(a)(2) and (3), the Council could recommend adjusting the final TACs, if warranted, based on the biological condition of groundfish stocks or a variety of socioeconomic considerations, or if required to cause the sum of TACs to fall within the OY range.

Potential Changes Between Proposed and Final Specifications

In previous years, the most significant changes (relative to the amount of assessed tonnage of fish) to the OFLs and ABCs from the proposed to the final harvest specifications have been based on the most recent NMFS stock surveys. These surveys provide updated estimates of stock biomass and spatial distribution, and inform changes to the models used for producing stock assessments. At the September 2022 Plan Team meeting, NMFS scientists presented updated and new survey results. Scientists also discussed potential changes to assessment models, and accompanying preliminary stock estimates. At the October 2022 Council meeting, the SSC reviewed this information. Species and species groups with proposed changes to assessment models include sharks, pollock, other rockfish, demersal shelf rockfish, northern rockfish, dusky rockfish, and thornyhead rockfish. Model changes can result in changes to final OFLs, ABCs, and TACs.

In November 2022, the Plan Team will consider updated survey results and updated stock assessments for groundfish, which will be included in the draft 2022 SAFE report. If the 2022 SAFE report indicates that the stock biomass trend is increasing for a species, then the final 2023 and 2024 harvest specifications for that species may reflect an increase from the proposed harvest specifications. Conversely, if the 2022 SAFE report indicates that the stock biomass trend is decreasing for a species, then the final 2023 and 2024 harvest specifications may reflect a decrease from the proposed harvest specifications.

The proposed 2023 and 2024 OFLs and ABCs are based on the best available biological and scientific information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods used to calculate stock biomass. The FMP specifies the tiers to be used to calculate OFLs and ABCs. The tiers applicable to a particular stock or stock complex are determined by the level of reliable information available to the fisheries scientists. This information is categorized into a successive series of six tiers to define OFLs and ABCs, with Tier 1 representing the highest level of information quality available and Tier 6 representing the lowest level of information quality available. The Plan Team used the FMP tier structure to calculate OFLs and ABCs for each groundfish species. The SSC adopted the proposed 2023 and 2024 OFLs and ABCs recommended by the Plan Team for all groundfish species. The proposed 2023 and 2024 TACs are based on the best available biological and socioeconomic information. The Council adopted the SSC's OFL and ABC recommendations and the AP's TAC recommendations for all groundfish species.

Specification and Apportionment of TAC Amounts

The Council recommended proposed 2023 and 2024 TACs that are equal to proposed ABCs for all species and species groups, with the exception of pollock for the combined Western and Central GOA and West Yakutat District area, Pacific cod, shallow-water flatfish in the Western GOA, arrowtooth flounder in the Western GOA and the Southeast Outside (SEO) District, flathead sole in the Western and Central GOA, Atka mackerel, and ''other rockfish'' in the SEO District.

The combined Western and Central Regulatory Areas and the West Yakutat (WYK) District of the Eastern Regulatory Area (the W/C/WYK) pollock TAC and the GOA Pacific cod TACs are set to account for the State of Alaska's (State) guideline harvest levels (GHL) for the State waters pollock and Pacific cod fisheries so that the ABCs are not exceeded. The shallow-water flatfish, arrowtooth flounder, and flathead sole TACs are set to allow for increased harvest opportunities for these target species while conserving the halibut PSC limit for use in other fisheries. The Atka mackerel TAC is set to accommodate incidental catch amounts (ICA) in other fisheries. The ''other rockfish'' TAC in the SEO District of the Eastern Regulatory Area is set to reduce the amount of discards of the species in that complex. These reductions are described below.

NMFS's proposed apportionments of groundfish species are based on the distribution of biomass among the regulatory areas over which NMFS manages the species. Additional regulations govern the apportionment of pollock, Pacific cod, and sablefish. Additional detail on apportionments of pollock, Pacific cod, and sablefish are described below.

The ABC for the pollock stock in the W/C/WYK Regulatory Area accounts for the GHL established by the State for the Prince William Sound (PWS) pollock fishery. The Plan Team, SSC, AP, and Council have recommended that the sum of all State waters and Federal waters pollock removals from the GOA not exceed ABC recommendations. For 2023 and 2024, the Council recommended the W/C/WYK pollock ABC include the amount to account for the State's PWS GHL. At the November 2018 Plan Team meeting, State fisheries managers recommended setting the future PWS GHL at 2.5 percent of the annual W/C/WYK pollock ABC. For 2023, this yields a PWS pollock GHL of 3,298 mt, a decrease of 29 mt from the 2022 PWS GHL of 3,327 mt. After accounting for the PWS GHL, the 2023 and 2024 pollock ABC for the combined W/C/WYK areas is then apportioned among four statistical areas (Areas 610, 620, 630, and 640) as both ABCs and TACs, as described below and detailed in Table 1. The total ABCs and TACs for the four statistical areas, plus the State GHL, do not exceed the combined W/C/WYK ABC. The proposed W/C/WYK 2023 and 2024 pollock ABC is 131,912 mt, and the proposed TAC is 128,614 mt.

Apportionments of pollock to the W/C/WYK management areas are considered to be apportionments of annual catch limit (ACL) rather than apportionments of ABCs. This more accurately reflects that such apportionments address management concerns, rather than biological or conservation concerns. In addition, apportionments of the ACL in this manner allow NMFS to balance any transfer of TAC among Areas 610, 620, and 630 pursuant to § 679.20(a)(5)(iv)(B) to ensure that the combined W/C/WYK ACL, ABC, and TAC are not exceeded.

NMFS proposes pollock TACs in the Western (Area 610) and Central (Areas 620 and 630) Regulatory Areas and the West Yakutat (Area 640) and the SEO (Area 650) Districts of the GOA (see Table 1). NMFS also proposes seasonal apportionment of the annual pollock TAC in the Western and Central Regulatory Areas of the GOA among Statistical Areas 610, 620, and 630. These apportionments are divided equally among the following two seasons: the A season (January 20 through May 31) and the B season (September 1 through November 1) (§§ 679.23(d)(2) and 679.20(a)(5)(iv)). Additional detail is provided below; Table 2 lists these amounts.

The proposed 2023 and 2024 Pacific cod TACs are set to accommodate the State's GHLs for Pacific cod in State waters in the Western and Central Regulatory Areas, as well as in PWS (in the Eastern Regulatory Area) (see Table 1). The Plan Team, SSC, AP, and Council recommended that the sum of all State waters and Federal waters Pacific cod removals from the GOA not exceed ABC recommendations. Accordingly, the Council recommended the 2023 and 2024 Pacific cod TACs in

the Western, Central, and Eastern Regulatory Areas to account for State GHLs. Therefore, the proposed 2023 and 2024 Pacific cod TACs are less than the proposed ABCs by the following amounts: (1) Western GOA, 2,610 mt; (2) Central GOA, 4,321 mt; and (3) Eastern GOA, 682 mt. These amounts reflect the State's 2023 and 2024 GHLs in these areas, which are 30 percent of the Western GOA proposed ABC, and 25 percent of the Eastern and Central GOA proposed ABCs.

The Western and Central GOA Pacific cod TACs are allocated among various gear and operational sectors. NMFS also establishes seasonal apportionments of the annual Pacific cod TACs in the Western and Central Regulatory Areas. The Pacific cod sector and seasonal apportionments are discussed in detail in a subsequent section and in Table 4 of this rule.

The Council's recommendation for sablefish area apportionments takes into account the prohibition on the use of trawl gear in the SEO District of the Eastern Regulatory Area (§ 679.7(b)(1)) and makes available 5 percent of the Eastern Regulatory Area (WYK and SEO Districts combined) TAC to vessels using trawl gear for use as incidental catch in other trawl groundfish fisheries in the WYK District (§ 679.20(a)(4)(i)). Additional detail is provided below. Tables 5 and 6 list the proposed 2023 and 2024 allocations of the sablefish TAC to fixed gear and trawl gear in the GOA.

For 2023 and 2024, the Council recommends, and NMFS proposes, the OFLs, ABCs, and TACs listed in Table 1. These amounts are consistent with the biological condition of groundfish stocks as described in the 2021 SAFE report. The proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs are adjusted for other biological and socioeconomic considerations. The sum of the proposed TACs for all GOA groundfish is 443,615 mt for 2023 and 2024, which is within the OY range specified by the FMP. These proposed amounts and apportionments by area, season, and sector are subject to change pending consideration of the 2022 SAFE report, public comment, and the Council's recommendations for the final 2023 and 2024 harvest specifications during its December 2022 meeting.

TABLE 1—PROPOSED 2023 AND 2024 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, AND EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICT OF THE GULF OF ALASKA

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
Pollock [2]	Shumagin (610)	n/a	23,506	23,506
	Chirikof (620)	n/a	68,642	68,642
	Kodiak (630)	n/a	29,803	29,803
	WYK (640)	n/a	6,663	6,663
	W/C/WYK (subtotal)	153,097	131,912	128,614
	SEO (650)	15,150	11,363	11,363
	Total	168,247	143,275	139,977
Pacific cod [3]	W	n/a	8,699	6,089
	C	n/a	17,282	12,962
	E	n/a	2,727	2,045
	Total	34,673	28,708	21,096
Sablefish [4]	W	n/a	3,951	3,951
	C	n/a	9,495	9,495
	WYK	n/a	3,159	3,159
	SEO	n/a	5,398	5,398
	Subtotal TAC	n/a	n/a	22,003
	Total	42,520	36,318	n/a
Shallow-water flatfish [5]	W	n/a	22,464	13,250
	C	n/a	26,743	26,743
	WYK	n/a	2,674	2,674
	SEO	n/a	1,605	1,605
	Total	65,676	53,486	44,272
Deep-water flatfish [6]	W	n/a	256	256
	C	n/a	2,105	2,105
	WYK	n/a	1,408	1,408
	SEO	n/a	2,049	2,049
	Total	6,920	5,818	5,818
Rex sole	W	n/a	3,222	3,222
	C	n/a	13,054	13,054
	WYK	n/a	1,439	1,439
	SEO	n/a	2,879	2,879
	Total	25,049	20,594	20,594

TABLE 1—PROPOSED 2023 AND 2024 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, AND EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICT OF THE GULF OF ALASKA—Continued

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
Arrowtooth flounder	W	n/a	33,214	14,500
	C	n/a	67,493	67,493
	WYK	n/a	6,619	6,619
	SEO	n/a	10,875	6,900
	Total	141,231	118,201	95,512
Flathead sole	W	n/a	14,708	8,650
	C	n/a	21,962	15,400
	WYK	n/a	1,506	1,506
	SEO	n/a	1,870	1,870
	Total	48,757	40,046	27,426
Pacific ocean perch [7]	W	n/a	2,523	2,523
	C	n/a	29,869	29,869
	WYK	n/a	1,366	1,366
	W/C/WYK	40,211	33,758	33,758
	SEO	3,985	3,346	3,346
	Total	44,196	37,104	37,104
Northern rockfish [8]	W	n/a	1,859	1,859
	C	n/a	3,061	3,061
	E	n/a	.....	.....
	Total	5,874	4,920	4,920
Shortraker rockfish [9]	W	n/a	51	51
	C	n/a	280	280
	E	n/a	374	374
	Total	940	705	705
Dusky rockfish [10]	W	n/a	259	259
	C	n/a	4,373	4,373
	WYK	n/a	412	412
	SEO	n/a	137	137
	Total	8,146	5,181	5,181
Rougheye and blackspotted rockfish [11]	W	n/a	182	182
	C	n/a	234	234
	E	n/a	365	365
	Total	937	781	781
Demersal shelf rockfish [12]	SEO	579	365	365
Thornyhead rockfish [13]	W	n/a	352	352
	C	n/a	910	910
	E	n/a	691	691
	Total	2,604	1,953	1,953
Other rockfish [14 15]	W/C combined	n/a	940	940
	WYK	n/a	370	370
	SEO	n/a	2,744	300
	Total	5,320	4,054	1,610
Atka mackerel	GW	6,200	4,700	3,000
Big skates [16]	W	n/a	591	591
	C	n/a	1,482	1,482
	E	n/a	794	794
	Total	3,822	2,867	2,867
Longnose skates [17]	W	n/a	151	151

TABLE 1—PROPOSED 2023 AND 2024 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, AND EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICT OF THE GULF OF ALASKA—Continued

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
	C	n/a	2,044	2,044
	E	n/a	517	517
	Total	3,616	2,712	2,712
Other skates [18]	GW	1,311	984	984
Sharks	GW	5,006	3,755	3,755
Octopuses	GW	1,307	980	980
Total		622,931	517,507	443,615

[1] Regulatory areas and districts are defined at § 679.2. (W = Western Gulf of Alaska; C = Central Gulf of Alaska; E = Eastern Gulf of Alaska; WYK = West Yakutat District; SEO = Southeast Outside District; GW = Gulfwide).

[2] The total for the W/C/WYK Regulatory Areas pollock ABC is 131,912 mt. After deducting 2.5 percent (3,298 mt) of that ABC for the State's pollock GHL fishery, the remaining pollock ABC of 128,614 mt (for the W/C/WYK Regulatory Areas) is apportioned among four statistical areas (Areas 610, 620, 630, and 640). These apportionments are considered subarea ACLs, rather than ABCs, for specification and reapportionment purposes. The ACLs in Areas 610, 620, and 630 are further divided by season, as detailed in Table 2 (proposed 2023 and 2024 seasonal biomass distribution of pollock in the Western and Central Regulatory Areas, area apportionments, and seasonal allowances). In the West Yakutat (Area 640) and Southeast Outside (Area 650) Districts of the Eastern Regulatory Area, pollock is not divided into seasonal allowances.

[3] The annual Pacific cod TAC is apportioned, after seasonal apportionment to the jig sector, as follows: (1) 63.84 percent to the A season and 36.16 percent to the B season and (2) 64.16 percent to the A season and 35.84 percent to the B season in the Western and Central Regulatory Areas of the GOA, respectively. The Pacific cod TAC in the Eastern Regulatory Area of the GOA is allocated 90 percent to vessels harvesting Pacific cod for processing by the inshore component and 10 percent to vessels harvesting Pacific cod for processing by the offshore component. Table 4 lists the proposed 2023 and 2024 Pacific cod seasonal apportionments and sector allocations.

[4] The sablefish OFL and ABC are set Alaska-wide (42,520 mt and 36,318 mt, respectively) and the GOA sablefish ABC is 22,003 mt. Additionally, sablefish is allocated only to trawl gear in 2024. Tables 5 and 6 list the proposed 2023 and 2024 allocations of sablefish TACs.

[5] "Shallow-water flatfish" means flatfish not including "deep-water flatfish," flathead sole, rex sole, or arrowtooth flounder.

[6] "Deep-water flatfish" means Dover sole, Greenland turbot, Kamchatka flounder, and deepsea sole.

[7] "Pacific ocean perch" means *Sebastes alutus.*

[8] "Northern rockfish" means *Sebastes polyspinous.* For management purposes the 1 mt apportionment of ABC to the WYK District of the Eastern Regulatory Area has been included in the "other rockfish" species group.

[9] "Shortraker rockfish" means *Sebastes borealis.*

[10] "Dusky rockfish" means *Sebastes variabilis.*

[11] "Rougheye and blackspotted rockfish" means *Sebastes aleutianus* (rougheye) and *Sebastes melanostictus* (blackspotted).

[12] "Demersal shelf rockfish" means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[13] "Thornyhead rockfish" means *Sebastolobus* species.

[14] "Other rockfish means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergray), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), *S. reedi* (yellowmouth), *S. entomelas* (widow), and *S. flavidus* (yellowtail). In the Eastern GOA only, "other rockfish" also includes northern rockfish (*S. polyspinous*).

[15] "Other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat District of the Eastern Regulatory Area means all rockfish species included in the "other rockfish" and demersal shelf rockfish categories. The "other rockfish" species group in the SEO District only includes other rockfish.

[16] "Big skates" means *Raja binoculata.*

[17] "Longnose skates" means *Raja rhina.*

[18] "Other skates" means *Bathyraja and Raja spp.*

Proposed Apportionment of Reserves

Section 679.20(b)(2) requires NMFS to set aside 20 percent of each TAC for pollock, Pacific cod, flatfish, sharks, and octopuses in reserve for possible apportionment at a later date during the fishing year. Section 679.20(b)(3) authorizes NMFS to reapportion all or part of these reserves. In 2022, NMFS reapportioned all of the reserves in the final harvest specifications. For 2023 and 2024, NMFS proposes reapportionment of each of the reserves for pollock, Pacific cod, flatfish, sharks, and octopuses back into the original TAC from which the reserve was derived. NMFS expects, based on recent harvest patterns, that such reserves will not be necessary and that the entire TAC for each of these species will be caught or are needed to promote efficient fisheries. The TACs in Table 1 reflect this proposed reapportionment of reserve amounts to the original TAC for these species and species groups, *i.e.,* each proposed TAC for the above-mentioned species or species groups contains the full TAC recommended by the Council.

Proposed Apportionments of Pollock TAC Among Seasons and Regulatory Areas, and Allocations for Processing by Inshore and Offshore Components

In the GOA, pollock is apportioned by season and area, and is further allocated for processing by inshore and offshore components. Pursuant to § 679.20(a)(5)(iv)(B), the annual pollock TAC specified for the Western and Central Regulatory Areas of the GOA is apportioned into two seasonal allowances of 50 percent. As established by § 679.23(d)(2), the A and B season allowances are available from January 20 through May 31 and September 1 through November 1, respectively.

The GOA pollock stock assessment continues to use a four-season methodology to determine pollock distribution in the Western and Central Regulatory Areas of the GOA to maintain continuity in the historical pollock apportionment time-series.

Pollock TACs in the Western and Central Regulatory Areas of the GOA are apportioned among Statistical Areas 610, 620, and 630 in proportion to the distribution of pollock biomass determined by the most recent NMFS surveys, pursuant to § 679.20(a)(5)(iv)(A). The pollock chapter of the 2021 SAFE report (see **ADDRESSES**) contains a comprehensive description of the apportionment and reasons for the minor changes from past apportionments. For purposes of specifying pollock between two seasons for the Western and Central Regulatory Areas of the GOA, NMFS has summed the A and B season apportionments and the C and D season apportionments as calculated in the 2021 GOA pollock assessment. This yields the seasonal amounts specified for the A season and the B season, respectively.

Within any fishing year, the amount by which a seasonal allowance is underharvested or overharvested may be added to, or subtracted from, subsequent seasonal allowances in a manner to be determined by the Regional Administrator (§ 679.20(a)(5)(iv)(B)). The rollover amount is limited to 20 percent of the subsequent seasonal TAC apportionment for the statistical area. Any unharvested pollock above the 20-percent limit could be further distributed to the subsequent season in the other statistical areas, in proportion to the estimated biomass to the subsequent season and in an amount no more than 20 percent of the seasonal TAC apportionment in those statistical areas (§ 679.20(a)(5)(iv)(B)). The proposed 2023 and 2024 pollock TACs in the WYK District of 6,663 mt and the SEO District of 11,363 mt are not allocated by season.

Table 2 lists the proposed 2023 and 2024 area apportionments and seasonal allowances of pollock in the Western and Central Regulatory Areas. The amounts of pollock for processing by the inshore and offshore components are not shown. Section 679.20(a)(6)(i) requires allocation of 100 percent of the pollock TAC in all regulatory areas and all seasonal allowances to vessels catching pollock for processing by the inshore component after subtraction of amounts projected by the Regional Administrator to be caught by, or delivered to, the offshore component incidental to directed fishing for other groundfish species. Thus, the amount of pollock available for harvest by vessels harvesting pollock for processing by the offshore component is the amount that will be taken as incidental catch during directed fishing for groundfish species other than pollock, up to the maximum retainable amounts allowed by § 679.20(e) and (f). At this time, these ICAs of pollock are unknown and will be determined during the fishing year during the course of fishing activities by the offshore component.

TABLE 2—PROPOSED 2023 AND 2024 DISTRIBUTION OF POLLOCK IN THE CENTRAL AND WESTERN REGULATORY AREAS OF THE GULF OF ALASKA; AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC [1]

[Values are rounded to the nearest metric ton]

Season [2]	Shumigan (area 610)	Chirikof (area 620)	Kodiak (area 630)	Total [3]
A (January 20–May 31)	1,122	51,845	8,009	60,976
B (September 1–November 1)	22,384	16,797	21,795	60,976
Annual Total	23,506	68,642	29,803	121,952

[1] Area apportionments and seasonal allowances may not total precisely due to rounding.
[2] As established by § 679.23(d)(2), the A and B season allowances are available from January 20 through May 31 and September 1 through November 1, respectively. The amounts of pollock for processing by the inshore and offshore components are not shown in this table.
[3] The West Yakutat and Southeast Outside District pollock TACs are not allocated by season and are not included in the total pollock TACs shown in this table.

Proposed Annual and Seasonal Apportionments of Pacific Cod TAC

Pursuant to § 679.20(a)(12)(i), NMFS proposes allocations for the 2023 and 2024 Pacific cod TACs in the Western and Central Regulatory Areas of the GOA among gear and operational sectors. NMFS also proposes seasonal apportionments of the Pacific cod TACs in the Western and Central Regulatory Areas. A portion of the annual TAC is apportioned to the A season for hook-and-line, pot, and jig gear from January 1 through June 10, and for trawl gear from January 20 through June 10. The remainder of the annual TAC is apportioned to the B season for jig gear from June 10 through December 31, for hook-and-line and pot gear from September 1 through December 31, and for trawl gear from September 1 through November 1 (§§ 679.23(d)(3) and 679.20(a)(12)). NMFS also proposes allocating the 2023 and 2024 Pacific cod TACs annually between the inshore (90 percent) and offshore (10 percent) components in the Eastern Regulatory Area of the GOA (§ 679.20(a)(6)(ii)).

In the Western GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among catcher vessels (CV) using hook-and-line gear, catcher/processors (CP) using hook-and-line gear, CVs using trawl gear, CPs using trawl gear, and vessels using pot gear (§ 679.20(a)(12)(i)(A)). In the Central GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among CVs less than 50 feet (15.2 meters (m)) in length overall using hook-and-line gear, CVs equal to or greater than 50 feet (15.2 m) in length overall using hook-and-line gear, CPs using hook-and-line gear, CVs using trawl gear, CPs using trawl gear, and vessels using pot gear (§ 679.20(a)(12)(i)(B)). For 2023 and 2024, NMFS proposes apportioning the jig sector allocations for the Western and Central GOA between the A season (60 percent) and the B season (40 percent) (§ 679.20(a)(12)(i)). Excluding seasonal apportionments to the jig gear sector, NMFS proposes apportioning the remainder of the annual Pacific cod TACs as follows: the seasonal apportionments of the annual TAC in the Western GOA are 63.84 percent to the A season and 36.16 percent to the B season, and in the Central GOA are 64.16 percent to the A season and 35.84 percent to the B season.

Under § 679.20(a)(12)(ii), any overage or underage of the Pacific cod allowance from the A season may be subtracted from, or added to, the subsequent B season allowance. In addition, any portion of the hook-and-line, trawl, pot, or jig sector allocations that is determined by NMFS as likely to go unharvested by a sector may be reallocated to other sectors for harvest during the remainder of the fishing year.

Pursuant to § 679.20(a)(12)(i)(A) and (B), a portion of the annual Pacific cod TACs in the Western and Central GOA

will be allocated to vessels with a Federal fisheries permit that use jig gear before the TACs are apportioned among other non-jig sectors. In accordance with the FMP, the annual jig sector allocations may increase to up to 6 percent of the annual Western and Central GOA Pacific cod TACs, depending on the annual performance of the jig sector (see Table 1 of Amendment 83 to the FMP for a detailed discussion of the jig sector allocation process (76 FR 74670, December 1, 2011)). Jig sector allocation increases are established for a minimum of 2 years.

NMFS has evaluated the historical harvest performance of the jig sector in the Western and Central GOA, and is proposing the 2023 and 2024 Pacific cod apportionments to this sector based on its historical harvest performance through 2021. For 2023 and 2024, NMFS proposes that the jig sector receive 3.5 percent of the annual Pacific cod TAC in the Western GOA. The 2023 and 2024 allocations consist of a base allocation of 1.5 percent of the Western GOA Pacific cod TAC, and prior historical harvest performance increases of 2.0 percent. For 2023 and 2024, NMFS also proposes that the jig sector receive 1.0 percent of the annual Pacific cod TAC in the Central GOA. The 2023 and 2024 allocations consist of a base allocation of 1.0 percent, and no additional performance increase in the Central GOA. The 2014 through 2022 Pacific cod jig allocations, catch, and percent allocation changes are listed in Table 3.

TABLE 3—SUMMARY OF WESTERN GOA AND CENTRAL GOA PACIFIC COD CATCH BY JIG GEAR IN 2014 THROUGH 2022, AND CORRESPONDING PERCENT ALLOCATION CHANGES

Area	Year	Initial percent of TAC	Initial TAC allocation	Catch (mt)	Percent of initial allocation	>90% of initial allocation?	Change to percent allocation
Western GOA	2014	2.5	573	785	137	Y	Increase 1%.
	2015	3.5	948	55	6	N	None.
	2016	3.5	992	52	5	N	Decrease 1%.
	2017	2.5	635	49	8	N	Decrease 1%.
	2018	1.5	125	121	97	Y	Increase 1%.
	2019	2.5	134	134	100	Y	Increase 1%.
	2020	n/a					
	2021	3.5	195	26	13	N	None.
	2022	3.5	195	26	13	N	None.
Central GOA	2014	2.0	797	262	33	N	Decrease 1%.
	2015	1.0	460	355	77	N	None.
	2016	1.0	370	267	72	N	None.
	2017	1.0	331	18	6	N	None.
	2018	1.0	61	0	0	N	None.
	2019	1.0	58	30	52	N	None.
	2020	n/a					
	2021	1.0	102	26	26	N	None.
	2022	1.0	102	26	26	N	None.

NMFS will re-evaluate the annual 2022 harvest performance of the jig sector in the Western and Central GOA when the 2022 fishing year is complete to determine whether to change the jig sector allocations proposed by this action in conjunction with the final 2023 and 2024 harvest specifications. The current catch through October 2022 by the Western GOA jig sector indicates that the Pacific cod allocation percentage to this sector would probably decrease in 2022 to 2.5 percent. Also, the current catch by the Central GOA jig sector indicates that this sector's Pacific cod allocation percentage would not change in 2022, and would remain at 1 percent. Table 4 lists the seasonal apportionments and allocations of the proposed 2023 and 2024 Pacific cod TACs.

TABLE 4—PROPOSED 2023 AND 2024 SEASONAL APPORTIONMENTS AND ALLOCATIONS OF PACIFIC COD TAC AMOUNTS IN THE GOA; ALLOCATIONS TO THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A season		B season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA:					
Jig (3.5% of TAC)	213	N/A	128	N/A	85
Hook-and-line CV	82	0.70	41	0.70	41
Hook-and-line CP	1,163	10.90	640	8.90	523
Trawl CV	2,256	31.54	1,853	6.86	403
Trawl CP	141	0.90	53	1.50	88
Pot CV and Pot CP	2,233	19.80	1,163	18.20	1,069
Total	6,089	63.84	3,879	36.16	2,210
Central GOA:					

TABLE 4—PROPOSED 2023 AND 2024 SEASONAL APPORTIONMENTS AND ALLOCATIONS OF PACIFIC COD TAC AMOUNTS IN THE GOA; ALLOCATIONS TO THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS—Continued

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A season		B season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Jig (1.0% of TAC)	130	N/A	78	N/A	52
Hook-and-line <50 CV	1,874	9.32	1,195	5.29	678
Hook-and-line ≥50 CV	861	5.61	720	1.10	141
Hook-and-line CP	655	4.11	527	1.00	128
Trawl CV [1]	5,336	25.29	3,246	16.29	2,090
Trawl CP	539	2.00	257	2.19	282
Pot CV and Pot CP	3,568	17.83	2,288	9.97	1,280
Total	12,962	64.16	8,311	35.84	4,651
Eastern GOA		Inshore (90% of Annual TAC)		Offshore (10% of Annual TAC)	
	2,045	1,841		205	

[1] Trawl catcher vessels participating in Rockfish Program cooperatives receive 3.81 percent, or 494 mt, of the annual Central GOA Pacific cod TAC (see Table 28c to 50 CFR part 679). This apportionment is deducted from the Trawl CV B season allowance (see Table 9: Proposed 2023 and 2024 Apportionments of Rockfish Secondary Species in the Central GOA and Table 28c to 50 CFR part 679).

Proposed Allocations of the Sablefish TAC Amounts to Vessels Using Fixed Gear and Trawl Gear

Section 679.20(a)(4)(i) and (ii) requires allocations of sablefish TACs for each of the regulatory areas and districts to fixed and trawl gear. In the Western and Central Regulatory Areas, 80 percent of each TAC is allocated to fixed gear, and 20 percent of each TAC is allocated to trawl gear. In the Eastern Regulatory Area, 95 percent of the TAC is allocated to fixed gear, and 5 percent is allocated to trawl gear. The trawl gear allocation in the Eastern Regulatory Area may be used only to support incidental catch of sablefish while directed fishing for other target species using trawl gear (§ 679.20(a)(4)(i)).

In recognition of the prohibition against trawl gear in the SEO District of the Eastern Regulatory Area, the Council recommended, and NMFS proposes, specifying for incidental catch the allocation of 5 percent of the Eastern Regulatory Area sablefish (WYK and SEO Districts combined) TAC to trawl gear in the WYK District of the Eastern Regulatory Area. The remainder of the WYK District sablefish TAC is allocated to vessels using fixed gear. This proposed action allocates 100 percent of the sablefish TAC in the SEO District to vessels using fixed gear. This results in proposed 2023 allocations of 428 mt to trawl gear and 2,731 mt to fixed gear in the WYK District, a proposed 2023 allocation of 5,398 mt to fixed gear in the SEO District, and a proposed 2024 allocation of 428 mt to trawl gear in the WYK District. Table 5 lists the allocations of the proposed 2023 sablefish TACs to fixed and trawl gear. Table 6 lists the allocations of the proposed 2024 sablefish TACs to trawl gear.

The Council recommended that the trawl sablefish TAC be established for 2 years so that retention of incidental catch of sablefish by trawl gear could commence in January in the second year of the groundfish harvest specifications. Tables 5 and 6 list the proposed 2023 and 2024 trawl allocations, respectively.

The Council also recommended that the fixed gear sablefish TAC be established annually to ensure that the sablefish individual fishing quota (IFQ) fishery is conducted concurrently with the halibut IFQ fishery and is based on the most recent survey information. Since there is an annual assessment for sablefish and since the final harvest specifications are expected to be published before the IFQ season begins (typically, in early March), the Council recommended that the fixed gear sablefish TAC be set annually, rather than for 2 years, so that the best available scientific information could be considered in establishing the sablefish ABCs and TACs. Accordingly, Table 5 lists the proposed 2023 fixed gear allocations, and the 2024 fixed gear allocations will be specified in the 2024 and 2025 harvest specifications.

With the exception of the trawl allocations that are provided to the Rockfish Program (see Table 28c to 50 CFR part 679), directed fishing for sablefish with trawl gear is closed during the fishing year. Also, fishing for groundfish with trawl gear is prohibited prior to January 20 (§ 679.23(c)). Therefore, it is not likely that the sablefish allocation to trawl gear would be reached before the effective date of the final 2023 and 2024 harvest specifications.

TABLE 5—PROPOSED 2023 SABLEFISH TAC AMOUNTS IN THE GULF OF ALASKA AND ALLOCATIONS TO FIXED AND TRAWL GEAR

[Values are rounded to the nearest metric ton]

Area/district	TAC	Fixed gear allocation	Trawl allocation
Western	3,951	3,161	790
Central [1]	9,495	7,596	1,899
West Yakutat [2]	3,159	2,731	428

TABLE 5—PROPOSED 2023 SABLEFISH TAC AMOUNTS IN THE GULF OF ALASKA AND ALLOCATIONS TO FIXED AND TRAWL GEAR—Continued

[Values are rounded to the nearest metric ton]

Area/district	TAC	Fixed gear allocation	Trawl allocation
Southeast Outside	5,398	5,398	0
Total	22,003	18,886	3,117

[1] The proposed trawl allocation of sablefish to the Central Regulatory Area is further apportioned to the Rockfish Program cooperatives (977 mt). See Table 9: Proposed 2023 and 2024 Apportionments of Rockfish Secondary Species in the Central GOA. This results in 922 mt being available for the non-Rockfish Program trawl fisheries.

[2] The proposed trawl allocation is based on allocating 5 percent of the Eastern Regulatory Area (West Yakutat and Southeast Outside Districts combined) sablefish TAC as incidental catch to trawl gear in the West Yakutat District.

TABLE 6—PROPOSED 2024 SABLEFISH TAC AMOUNTS IN THE GULF OF ALASKA AND ALLOCATION TO TRAWL GEAR [1]

[Values are rounded to the nearest metric ton]

Area/district	TAC	Fixed gear allocation	Trawl allocation
Western	3,951	n/a	790
Central [2]	9,495	n/a	1,899
West Yakutat [3]	3,159	n/a	428
Southeast Outside	5,398	n/a	0
Total	22,003	n/a	3,117

[1] The Council recommended that the proposed 2024 harvest specifications for the fixed gear sablefish Individual Fishing Quota fisheries not be specified in the proposed 2023 and 2024 harvest specifications.

[2] The proposed trawl allocation of sablefish to the Central Regulatory Area is further apportioned to the Rockfish Program cooperatives (977 mt). See Table 9: Proposed 2023 and 2024 Apportionments of Rockfish Secondary Species in the Central GOA. This results in 922 mt being available for the non-Rockfish Program trawl fisheries.

[3] The proposed trawl allocation is based on allocating 5 percent of the Eastern Regulatory Area (West Yakutat and Southeast Outside Districts combined) sablefish TAC as incidental catch to trawl gear in the West Yakutat District.

Proposed Allocations, Apportionments, and Sideboard Limitations for the Rockfish Program

These proposed 2023 and 2024 harvest specifications for the GOA include the fishery cooperative allocations and sideboard limitations established by the Rockfish Program. Program participants are primarily trawl CVs and trawl CPs, with limited participation by vessels using longline gear. The Rockfish Program assigns quota share and cooperative quota to trawl participants for primary species (Pacific ocean perch, northern rockfish, and dusky rockfish) and secondary species (Pacific cod, rougheye rockfish, sablefish, shortraker rockfish, and thornyhead rockfish), allows a participant holding a license limitation program (LLP) license with rockfish quota share to form a rockfish cooperative with other persons, and allows holders of CP LLP licenses to opt out of the fishery. The Rockfish Program also has an entry level fishery for rockfish primary species for vessels using longline gear. Longline gear includes hook-and-line, jig, troll, and handline gear.

Under the Rockfish Program, rockfish primary species in the Central GOA are allocated to participants after deducting for incidental catch needs in other directed fisheries (§ 679.81(a)(2)). Participants in the Rockfish Program also receive a portion of the Central GOA TAC of specific secondary species. In addition to groundfish species, the Rockfish Program allocates a portion of the halibut PSC limit (191 mt) from the third season deep-water species fishery allowance for the GOA trawl fisheries to Rockfish Program participants (§ 679.81(d) and Table 28d to 50 CFR part 679). The Rockfish Program also establishes sideboard limits to restrict the ability of harvesters operating under the Rockfish Program to increase their participation in other, non-Rockfish Program fisheries. These restrictions and halibut PSC limits are discussed in the *Rockfish Program Groundfish Sideboard and Halibut PSC Limitations* section of this rule.

Section 679.81(a)(2)(ii) and Table 28e to 50 CFR part 679 require allocations of 5 mt of Pacific ocean perch, 5 mt of northern rockfish, and 50 mt of dusky rockfish to the entry level longline fishery in 2023 and 2024. The allocation for the entry level longline fishery may increase incrementally each year if the catch exceeds 90 percent of the allocation of a species. The incremental increase in the allocation would continue each year until it reaches the maximum percentage of the TAC for that species. In 2022, the catch for all three primary species did not exceed 90 percent of any allocated rockfish species. Therefore, NMFS is not proposing any increases to the entry level longline fishery 2023 and 2024 allocations in the Central GOA. The remainder of the TACs for the rockfish primary species, after subtracting the ICAs, would be allocated to the CV and CP cooperatives (§ 679.81(a)(2)(iii)). Table 7 lists the allocations of the proposed 2023 and 2024 TACs for each rockfish primary species to the entry level longline fishery, the potential incremental increases for future years, and the maximum percentages of the TACs for the entry level longline fishery.

TABLE 7—PROPOSED 2023 AND 2024 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES TO THE ENTRY LEVEL LONGLINE FISHERY IN THE CENTRAL GULF OF ALASKA

Rockfish primary species	Proposed 2023 and 2024 allocations	Incremental increase in 2024 if >90 percent of 2023 allocation is harvested	Up to maximum percent of each TAC of
Pacific ocean perch	5 metric tons	5 metric tons	1
Northern rockfish	5 metric tons	5 metric tons	2
Dusky rockfish	50 metric tons	20 metric tons	5

Section 679.81 requires allocations of rockfish primary species among various sectors of the Rockfish Program. Table 8 lists the proposed 2023 and 2024 allocations of rockfish primary species in the Central GOA to the entry level longline fishery, and rockfish CV and CP cooperatives in the Rockfish Program. NMFS also proposes setting aside ICAs for other directed fisheries in the Central GOA of 2,500 mt of Pacific ocean perch, 300 mt of northern rockfish, and 250 mt of dusky rockfish. These amounts are based on recent average incidental catches in the Central GOA by other groundfish fisheries.

Allocations among vessels belonging to CV or CP cooperatives are not included in these proposed harvest specifications. Rockfish Program applications for CV cooperatives and CP cooperatives are not due to NMFS until March 1 of each calendar year; therefore, NMFS cannot calculate 2023 and 2024 allocations in conjunction with these proposed harvest specifications. NMFS will post the 2023 allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports#central-goa-rockfish* when they become available after March 1.

TABLE 8—PROPOSED 2023 AND 2024 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES IN THE CENTRAL GULF OF ALASKA TO THE ENTRY LEVEL LONGLINE FISHERY AND ROCKFISH COOPERATIVES IN THE ROCKFISH PROGRAM

[Values are rounded to the nearest metric ton]

Rockfish primary species	Central GOA TAC	Incidental catch allowance (ICA)	TAC minus ICA	Allocation to the entry level longline [1] fishery	Allocation to the Rockfish cooperatives [2]
Pacific ocean perch	29,869	2,500	27,369	5	27,364
Northern rockfish	3,061	300	2,761	5	2,756
Dusky rockfish	4,373	250	4,123	50	4,073
Total	37,303	3,050	34,253	60	34,193

[1] Longline gear includes hook-and-line, jig, troll, and handline gear (50 CFR 679.2).
[2] Rockfish cooperatives include vessels in CV and CP cooperatives (50 CFR 679.81).

Section 679.81(c) and Table 28c to 50 CFR part 679 requires allocations of rockfish secondary species to CV and CP cooperatives in the Central GOA. CV cooperatives receive allocations of Pacific cod, sablefish from the trawl gear allocation, and thornyhead rockfish. CP cooperatives receive allocations of sablefish from the trawl gear allocation, rougheye and blackspotted rockfish, shortraker rockfish, and thornyhead rockfish. Table 9 lists the apportionments of the proposed 2023 and 2024 TACs of rockfish secondary species in the Central GOA to CV and CP cooperatives.

TABLE 9—PROPOSED 2023 AND 2024 APPORTIONMENTS OF ROCKFISH SECONDARY SPECIES IN THE CENTRAL GOA TO CATCHER VESSEL AND CATCHER/PROCESSOR COOPERATIVES

[Values are in metric tons]

Rockfish secondary species	Central GOA annual TAC	Catcher vessel cooperatives		Catcher/processor cooperatives	
		Percentage of TAC	Apportionment (mt)	Percentage of TAC	Apportionment (mt)
Pacific cod	12,962	3.81	494	0.00	0
Sablefish	9,495	6.78	644	3.51	333
Shortraker rockfish	280	0.00	0	40.00	112
Rougheye and blackspotted rockfish	234	0.00	0	58.87	138
Thornyhead rockfish	910	7.84	71	26.50	241

Halibut PSC Limits

Section 679.21(d) establishes annual halibut PSC limit apportionments to trawl and hook-and-line gear, and authorizes the establishment of apportionments for pot gear. In October 2022, the Council recommended, and NMFS proposes, halibut PSC limits of 1,705 mt for trawl gear, 257 mt for hook-and-line gear, and 9 mt for the demersal shelf rockfish (DSR) fishery in the SEO District for both 2023 and 2024.

The DSR fishery in the SEO District is defined at § 679.21(d)(2)(ii)(A). This fishery is apportioned 9 mt of the halibut PSC limit in recognition of its small-scale harvests of groundfish (§ 679.21(d)(2)(i)(A)). The separate halibut PSC limit for the DSR fishery is intended to prevent that fishery from being impacted from the halibut PSC incurred by other GOA fisheries. NMFS estimates low halibut bycatch in the DSR fishery because, (1) the duration of the DSR fisheries and the gear soak times are short; (2) the DSR fishery occurs in the winter when there is less overlap in the distribution of DSR and halibut; and (3) the directed commercial DSR fishery has a low DSR TAC. The Alaska Department of Fish and Game sets the commercial GHL for the DSR fishery after deducting, (1) estimates of DSR incidental catch in all fisheries (including halibut and subsistence); and (2) the allocation to the DSR sport fish fishery. In 2022, the commercial fishery for DSR was closed due to concerns about declining DSR biomass.

The FMP authorizes the Council to exempt specific gear from the halibut PSC limits. NMFS, after consultation with the Council, proposes to exempt pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from the non-trawl halibut PSC limit for 2023 and 2024. The Council recommended, and NMFS is proposing, these exemptions because, (1) pot gear fisheries have low annual halibut bycatch mortality; (2) IFQ program regulations prohibit discard of halibut if any halibut IFQ permit holder on board a CV holds unused halibut IFQ for that vessel category and the IFQ regulatory area in which the vessel is operating (§ 679.7(f)(11)); (3) some sablefish IFQ permit holders hold halibut IFQ permits and are therefore required to retain the halibut they catch while fishing sablefish IFQ; and (4) NMFS estimates negligible halibut mortality for the jig gear fisheries given the small amount of groundfish harvested by jig gear, the selective nature of jig gear, and the high survival rates of halibut caught and released with jig gear.

The best available information on estimated halibut bycatch consists of data collected by fisheries observers during 2022. The calculated halibut bycatch mortality through November 3, 2022 is 354 mt for trawl gear and 34 mt for hook-and-line gear, for a total halibut mortality of 388 mt. This halibut mortality was calculated using groundfish and IFQ halibut catch data from the NMFS Alaska Region's catch accounting system. This accounting system contains historical and recent catch information compiled from each Alaska groundfish and IFQ halibut fishery.

Section 679.21(d)(4)(i) and (ii) authorizes NMFS to seasonally apportion the halibut PSC limits after consultation with the Council. The FMP and regulations require that the Council and NMFS consider the following information in seasonally apportioning halibut PSC limits: (1) seasonal distribution of halibut; (2) seasonal distribution of target groundfish species relative to halibut distribution; (3) expected halibut bycatch needs on a seasonal basis relative to changes in halibut biomass and expected catch of target groundfish species; (4) expected bycatch rates on a seasonal basis; (5) expected changes in directed groundfish fishing seasons; (6) expected actual start of fishing effort; and (7) economic effects of establishing seasonal halibut allocations on segments of the target groundfish industry. Based on public comment, information presented in the 2022 SAFE report, NMFS catch data, State catch data, and International Pacific Halibut Commission (IPHC) stock assessment and mortality data, the Council may recommend, or NMFS may make changes, to the seasonal, gear-type, or fishery category apportionments of halibut PSC limits for the final 2023 and 2024 harvest specifications pursuant to § 679.21(d)(1) and (4).

The final 2022 and 2023 harvest specifications (87 FR 11599, March 2, 2022) lists the Council's and NMFS's seasonal apportionments based on these FMP and regulatory considerations with respect to halibut PSC limits. The Council's and NMFS's seasonal apportionments for these proposed 2023 and 2024 harvest specifications are unchanged from the final 2022 and 2023 harvest specifications. Table 10 lists the proposed 2023 and 2024 Pacific halibut PSC limits, allowances, and apportionments. The halibut PSC limits in Tables 10, 11, and 12 reflect the halibut PSC limits set forth at § 679.21(d)(2) and (3). Section 679.21(d)(4)(iii) and (iv) specifies that any underages or overages of a seasonal apportionment of a halibut PSC limit will be added to or deducted from the next respective seasonal apportionment within the fishing year.

TABLE 10—PROPOSED 2023 AND 2024 PACIFIC HALIBUT PSC LIMITS, ALLOWANCES, AND APPORTIONMENTS

[Values are in metric tons]

Trawl gear			Hook-and-line gear [1]				
			Other than DSR			DSR	
Season	Percent	Amount	Season	Percent	Amount	Season	Amount
January 20–April 1	30.5	519	January 1–June 10	86	221	January 1–December 31	9
April 1–July 1	20	341	June 10–September 1	2	5		
July 1–August 1	27	462	September 1–December 31.	12	31		
August 1–October 1	7.5	128					
October 1–December 31	15	256					
Total		1,705			257		9

[1] The Pacific halibut prohibited species catch (PSC) limit for hook-and-line gear is allocated to the demersal shelf rockfish (DSR) fishery in the SEO District and to hook-and-line fisheries other than the DSR fishery. The Council recommended, and NMFS proposes, that the hook-and-line sablefish IFQ fishery, and the pot and jig gear groundfish fisheries, be exempt from halibut PSC limits.

Section 679.21(d)(3)(ii) authorizes further apportionment of the trawl halibut PSC limit as bycatch allowances to trawl fishery categories listed in § 679.21(d)(3)(iii). The annual apportionments are based on each category's share of the anticipated halibut bycatch mortality during a fishing year and optimization of the total amount of groundfish harvest under the halibut PSC limit. The fishery categories for the trawl halibut PSC limits are: (1) a deep-water species fishery, composed of sablefish, rockfish, deep-water flatfish, rex sole, and arrowtooth flounder; and (2) a shallow-water species fishery, composed of pollock, Pacific cod, shallow-water flatfish, flathead sole, Atka mackerel, skates, and ''other species'' (sharks and octopuses) (§ 679.21(d)(3)(iii)). Halibut mortality incurred while directed fishing for skates with trawl gear accrues towards the shallow-water species fishery halibut PSC limit (69 FR 26320, May 12, 2004).

NMFS will combine available trawl halibut PSC limit apportionments in part of the second season deep-water and shallow-water species fisheries for use in either fishery from May 15 through June 30 (§ 679.21(d)(4)(iii)(D)). This is intended to maintain groundfish harvest while minimizing halibut bycatch by these sectors to the extent practicable. This provides the trawl gear deep-water and shallow-water species fisheries additional flexibility and the incentive to participate in fisheries at times of the year that may have lower halibut PSC rates relative to other times of the year.

Table 11 lists the proposed 2023 and 2024 seasonal apportionments of trawl halibut PSC limits between the trawl gear deep-water and the shallow-water species fisheries.

Table 28d to 50 CFR part 679 specifies the amount of the trawl halibut PSC limit that is assigned to the CV and CP sectors that are participating in the Central GOA Rockfish Program. This includes 117 mt of halibut PSC limit to the CV sector and 74 mt of halibut PSC limit to the CP sector. These amounts are allocated from the trawl deep-water species fishery's halibut PSC third seasonal apportionment. After the combined CV and CP halibut PSC limit allocation of 191 mt to the Rockfish Program, 150 mt remains for the trawl deep-water species fishery's halibut PSC third seasonal apportionment.

Section 679.21(d)(4)(iii)(B) limits the amount of the halibut PSC limit allocated to Rockfish Program participants that could be re-apportioned to the general GOA trawl fisheries for the last seasonal apportionment during the current fishing year to no more than 55 percent of the unused annual halibut PSC limit apportioned to Rockfish Program participants. The remainder of the unused Rockfish Program halibut PSC limit is unavailable for use by any person for the remainder of the fishing year (§ 679.21(d)(4)(iii)(C)).

TABLE 11—PROPOSED 2023 AND 2024 APPORTIONMENT OF THE PACIFIC HALIBUT PSC LIMITS BETWEEN THE TRAWL GEAR SHALLOW-WATER AND DEEP-WATER SPECIES FISHERY CATEGORIES

[Values are in metric tons]

Season	Shallow-water	Deep-water [1]	Total
January 20–April 1	384	135	519
April 1–July 1	85	256	341
July 1–August 1	121	341	462
August 1–October 1	53	75	128
Subtotal, January 20–October 1	643	807	1,450
October 1–December 31 [2]	.....	.....	256
Total	.....	.....	1,705

[1] Vessels participating in cooperatives in the Central GOA Rockfish Program will receive 191 mt of the third season (July 1 through August 1) deep-water species fishery halibut PSC apportionment.

[2] There is no apportionment between trawl shallow-water and deep-water species fisheries during the fifth season (October 1 through December 31).

Section 679.21(d)(2)(i)(B) requires that the ''other hook-and-line fishery'' halibut PSC limit apportionment to vessels using hook-and-line gear must be apportioned between CVs and CPs in accordance with § 679.21(d)(2)(iii) in conjunction with these harvest specifications. A comprehensive description and example of the calculations necessary to apportion the ''other hook-and-line fishery'' halibut PSC limit between the hook-and-line CV and CP sectors were included in the proposed rule to implement Amendment 83 to the FMP (76 FR 44700, July 26, 2011) and are not repeated here.

Pursuant to § 679.21(d)(2)(iii), the hook-and-line halibut PSC limit for the ''other hook-and-line fishery'' is apportioned between the CV and CP sectors in proportion to the total Western and Central GOA Pacific cod allocations, which vary annually based on the proportion of the Pacific cod biomass between the Western, Central, and Eastern GOA. Pacific cod is apportioned among these three management areas based on the percentage of overall biomass per area, as calculated in the 2021 Pacific cod stock assessment. Updated information in the final 2021 SAFE report describes this distributional calculation, which allocates ABC among GOA regulatory areas on the basis of the three most recent stock surveys. For 2023 and 2024, the proposed distribution of the total GOA Pacific cod ABC is 30.3 percent to the Western GOA, 60.2 percent to the Central GOA, and 9.5 percent to the Eastern GOA. Therefore, the calculations made in accordance with § 679.21(d)(2)(iii) incorporate the most recent information on GOA Pacific cod distribution and allocations with respect to the proposed annual halibut PSC limits for the CV and CP hook-and-line sectors. Additionally, the annual halibut PSC limits for both the CV and CP sectors of the ''other hook-and-line fishery'' are proposed to be divided into three seasonal apportionments, using seasonal percentages of 86 percent, 2 percent, and 12 percent.

For 2023 and 2024, NMFS proposes annual halibut PSC limits of 150 mt and 107 mt to the hook-and-line CV and hook-and-line CP sectors, respectively. Table 12 lists the proposed 2023 and 2024 apportionments of halibut PSC limits between the hook-and-line CV

and the hook-and-line CP sectors of the ''other hook-and-line fishery.''

No later than November 1 of each year, NMFS will calculate the projected unused amount of halibut PSC limit by either of the CV or CP hook-and-line sectors of the ''other hook-and-line fishery'' for the remainder of the year. The projected unused amount of halibut PSC limit is made available to the other hook-and-line sector for the remainder of that fishing year (§ 679.21(d)(2)(iii)(C)), if NMFS determines that an additional amount of halibut PSC is necessary for that sector to continue its directed fishing operations.

TABLE 12—PROPOSED 2023 AND 2024 APPORTIONMENTS OF THE ''OTHER HOOK-AND-LINE FISHERY'' ANNUAL HALIBUT PSC ALLOWANCE BETWEEN THE HOOK-AND-LINE GEAR CATCHER VESSEL AND CATCHER/PROCESSOR SECTORS

[Values are in metric tons]

''Other than DSR'' allowance	Hook-and-line sector	Sector annual amount	Season	Seasonal percentage	Sector seasonal amount
257	Catcher Vessel	150	January 1–June 10	86	129
			June 10–September 1	2	3
			September 1–December 31	12	18
	Catcher/Processor	107	January 1–June 10	86	92
			June 10–September 1	2	2
			September 1–December 31	12	13

Halibut Discard Mortality Rates

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, halibut discard mortality rates (DMR), and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. Halibut incidental catch rates are based on observed estimates of halibut incidental catch in the groundfish fishery. DMRs are estimates of the proportion of incidentally caught halibut that do not survive after being returned to the sea. The cumulative halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. DMRs are estimated using the best scientific information available in conjunction with the annual GOA stock assessment process. The DMR methodology and findings are included as an appendix to the annual GOA groundfish SAFE report.

In 2016, the DMR estimation methodology underwent revisions per the Council's directive. An interagency halibut working group (IPHC, Council, and NMFS staff) developed improved estimation methods that have undergone review by the Plan Team, the SSC, and the Council. A summary of the revised methodology is contained in the GOA proposed 2017 and 2018 harvest specifications (81 FR 87881, December 6, 2016), and the comprehensive discussion of the working group's statistical methodology is available from the Council (see **ADDRESSES**). The DMR working group's revised methodology is intended to improve estimation accuracy, transparency, and transferability for calculating DMRs. The working group will continue to consider improvements to the methodology used to calculate halibut mortality, including potential changes to the reference period (the period of data used for calculating the DMRs). Future DMRs may change based on additional years of observer sampling, which could provide more recent and accurate data and which could improve the accuracy of estimation and progress on methodology. The methodology will continue to ensure that NMFS is using DMRs that more accurately reflect halibut mortality, which will inform the different sectors of their estimated halibut mortality and allow specific sectors to respond with methods that could reduce mortality and, eventually, the DMR for that sector.

In October 2022, the Council recommended halibut DMRs reviewed by the Plan Team and SSC, which are derived from the revised methodology.The proposed 2023 and 2024 DMRs use an updated 2-year reference period. The Council's motion incorrectly specified some of the proposed DMRs, but consistent with the Council's intent, NMFS is proposing the DMRs calculated by the Plan Team and reviewed by the SSC for the proposed 2023 and 2024 DMRs. Comparing the proposed 2023 and 2024 DMRs to the final DMRs from the final 2022 and 2023 harvest specifications, the proposed DMR for Rockfish Program CVs using non-pelagic trawl gear decreased to 55 percent from 66 percent, the proposed DMR non-Rockfish Program CVs using non-pelagic gear increased to 74 percent from 69 percent, the proposed DMR for CPs using hook-and-line gear decreased to 13 percent from 15 percent, the proposed DMR for CVs using hook-and-line gear decreased to 9 percent from 12 percent, and the proposed DMR for CPs and CVs using pot gear decreased to 27 percent from 29 percent. For pelagic trawl gear CVs and CPs, and non-pelagic trawl mothership and CPs, the DMRs remained the same. Table 13 lists the proposed 2023 and 2024 DMRs.

TABLE 13—PROPOSED 2023 AND 2024 DISCARD MORTALITY RATES FOR VESSELS FISHING IN THE GULF OF ALASKA

[Values are percent of halibut assumed to be dead]

Gear	Sector	Groundfish fishery	Halibut discard mortality rate (percent)
Pelagic trawl	Catcher vessel	All	100
	Catcher/processor	All	100
Non-pelagic trawl	Catcher vessel	Rockfish Program	55
	Catcher vessel	All others	74

TABLE 13—PROPOSED 2023 AND 2024 DISCARD MORTALITY RATES FOR VESSELS FISHING IN THE GULF OF ALASKA—Continued

[Values are percent of halibut assumed to be dead]

Gear	Sector	Groundfish fishery	Halibut discard mortality rate (percent)
	Mothership and catcher/processor	All	83
Hook-and-line	Catcher/processor	All	13
	Catcher vessel	All	9
Pot	Catcher vessel and catcher/processor	All	27

Chinook Salmon Prohibited Species Catch Limits

Section 679.21(h)(2) establishes separate Chinook salmon PSC limits in the Western and Central regulatory areas of the GOA in the trawl pollock directed fishery. These limits require that NMFS close directed fishing for pollock in the Western and Central GOA if the applicable Chinook salmon PSC limit is reached (§ 679.21(h)(8)). The annual Chinook salmon PSC limits in the trawl pollock directed fishery of 6,684 salmon in the Western GOA and 18,316 salmon in the Central GOA are set in § 679.21(h)(2)(i) and (ii).

Section 679.21(h)(3) established an initial annual PSC limit of 7,500 Chinook salmon for the non-pollock groundfish trawl fisheries in the Western and Central GOA. This limit is apportioned among the three sectors that conduct directed fishing for groundfish species other than pollock: 3,600 Chinook salmon to trawl CPs; 1,200 Chinook salmon to trawl CVs participating in the Rockfish Program; and 2,700 Chinook salmon to trawl CVs not participating in the Rockfish Program (§ 679.21(h)(4)). NMFS will monitor the Chinook salmon PSC in the trawl non-pollock GOA groundfish fisheries and close an applicable sector if it reaches its Chinook salmon PSC limit.

The Chinook salmon PSC limit for two sectors, trawl CPs and trawl CVs not participating in the Rockfish Program, may be increased in subsequent years based on the performance of these two sectors and their ability to minimize their use of their respective Chinook salmon PSC limits. If either or both of these two sectors limit its use of Chinook salmon PSC to a certain threshold amount in 2022 (3,120 for trawl CPs and 2,340 for non-Rockfish Program trawl CVs), that sector will receive an increase to its 2023 Chinook salmon PSC limit (4,080 for trawl CPs and 3,060 for non-Rockfish Program trawl CVs) (§ 679.21(h)(4)). NMFS will evaluate the annual Chinook salmon PSC by trawl CPs and non-Rockfish Program trawl CVs when the 2022 fishing year is complete to determine whether to increase the Chinook salmon PSC limits for these two sectors. Based on preliminary 2022 Chinook salmon PSC data, the trawl CP sector may receive an incremental increase of Chinook salmon PSC limit in 2023, and the non-Rockfish Program trawl CV sector may receive an incremental increase of Chinook salmon PSC limit in 2023. This evaluation will be completed in conjunction with the final 2023 and 2024 harvest specifications.

American Fisheries Act (AFA) CP and CV Groundfish Harvest and PSC Limits

Section 679.64 establishes groundfish harvesting and processing sideboard limits on AFA CPs and CVs in the GOA. These sideboard limits are necessary to protect the interests of fishermen and processors who do not directly benefit from the AFA from those fishermen and processors who receive exclusive harvesting and processing privileges under the AFA. Section 679.7(k)(1)(ii) prohibits listed AFA CPs and CPs designated on a listed AFA CP permit from harvesting any species of fish in the GOA. Additionally, § 679.7(k)(1)(iv) prohibits listed AFA CPs and CPs designated on a listed AFA CP permit from processing any pollock harvested in a directed pollock fishery in the GOA and any groundfish harvested in Statistical Area 630 of the GOA.

AFA CVs that are less than 125 feet (38.1 meters) length overall, have annual landings of pollock in the Bering Sea and Aleutian Islands of less than 5,100 mt, and have made at least 40 landings of GOA groundfish from 1995 through 1997 are exempt from GOA CV groundfish sideboard limits under § 679.64(b)(2)(ii). Sideboard limits for non-exempt AFA CVs in the GOA are based on their traditional harvest levels of TAC in groundfish fisheries covered by the FMP. Section 679.64(b)(3)(iv) establishes the CV groundfish sideboard limits in the GOA based on the aggregate retained catch by non-exempt AFA CVs of each sideboard species from 1995 through 1997 divided by the TAC for that species over the same period.

NMFS published a final rule (84 FR 2723, February 8, 2019) that implemented regulations to prohibit non-exempt AFA CVs from directed fishing for specific groundfish species or species groups subject to sideboard limits (§ 679.20(d)(1)(iv)(D) and Table 56 to 50 CFR part 679). Sideboard limits not subject to the final rule continue to be calculated and included in the GOA annual harvest specifications.

Table 14 lists the proposed 2023 and 2024 groundfish sideboard limits for non-exempt AFA CVs. NMFS will deduct all targeted or incidental catch of sideboard species made by non-exempt AFA CVs from the sideboard limits listed in Table 14.

TABLE 14—PROPOSED 2023 AND 2024 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV) GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Apportionments by season/ gear	Area/component	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Proposed 2023 and 2024 TACs [3]	Proposed 2023 and 2024 non-exempt AFA CV sideboard limit
Pollock	A Season, January 20–May 31.	Shumagin (610)	0.6047	1,122	679
		Chirikof (620)	0.1167	51,845	6,050
		Kodiak (630)	0.2028	8,009	1,624
	B Season, September 1–November 1.	Shumagin (610)	0.6047	22,384	13,535
		Chirikof (620)	0.1167	16,797	1,960
		Kodiak (630)	0.2028	21,795	4,420
	Annual	WYK (640)	0.3495	6,663	2,329
		SEO (650)	0.3495	11,363	3,971
Pacific cod	A Season [1]	W	0.1331	3,879	516
	January 1–June 10	C	0.0692	8,311	575
	B Season [2], September 1–December 31.	W	0.1331	2,210	294
		C	0.0692	4,651	322
Flatfish, shallow-water	Annual	W	0.0156	13,250	207
		C	0.0587	26,743	1,570
Flatfish, deep-water	Annual	C	0.0647	2,105	136
		E	0.0128	3,457	44
Rex sole	Annual	C	0.0384	13,054	501
Arrowtooth flounder	Annual	C	0.0280	67,493	1,890
Flathead sole	Annual	C	0.0213	15,400	328
Pacific ocean perch	Annual	C	0.0748	29,869	2,234
		E	0.0466	4,712	220
Northern rockfish	Annual	C	0.0277	3,061	85

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.
[3] The Western and Central GOA and WYK District area apportionments of pollock are considered ACLs.

Non-Exempt AFA Catcher Vessel Halibut PSC Limits

The halibut PSC sideboard limits for non-exempt AFA CVs in the GOA are based on the aggregate retained groundfish catch by non-exempt AFA CVs in each PSC target category from 1995 through 1997 divided by the retained catch of all vessels in that fishery from 1995 through 1997 (§ 679.64(b)(4)(ii)). Table 15 lists the proposed 2023 and 2024 non-exempt AFA CV halibut PSC limits for vessels using trawl gear in the GOA.

TABLE 15—PROPOSED 2023 AND 2024 NON-EXEMPT AFA CV HALIBUT PSC SIDEBOARD LIMITS FOR VESSELS USING TRAWL GEAR IN THE GOA

[PSC limits are rounded to the nearest metric ton]

Season	Season dates	Fishery category	Ratio of 1995–1997 non-exempt AFA CV retained catch to total retained catch	Proposed 2023 and 2024 PSC limit	Proposed 2023 and 2024 non-exempt AFA CV PSC limit
1	January 20–April 1	shallow-water	0.340	384	131
		deep-water	0.070	135	9
2	April 1–July 1	shallow-water	0.340	85	29
		deep-water	0.070	256	18
3	July 1–August 1	shallow-water	0.340	121	41
		deep-water	0.070	341	24
4	August 1–October 1	shallow-water	0.340	53	18
		deep-water	0.070	75	5
5	October 1–December 31	all targets	0.205	256	52
Annual		Total shallow-water			219
		Total deep-water			56
		Grand Total, all seasons and categories		1,705	328

Non-AFA Crab Vessel Groundfish Harvest Limitations

Section 680.22 establishes groundfish sideboard limits for vessels with a history of participation in the Bering Sea snow crab fishery to prevent these vessels from using the increased flexibility provided by the Crab Rationalization (CR) Program to expand their level of participation in the GOA groundfish fisheries. Sideboard harvest limits restrict these vessels' catch to their collective historical landings in each GOA groundfish fishery (except the fixed-gear sablefish fishery). Sideboard limits also apply to landings made using an LLP license derived from the history of a restricted vessel, even if that LLP license is used on another vessel.

The basis for these sideboard harvest limits is described in detail in the final rules implementing the major provisions of the CR Program, including Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (Crab FMP) (70 FR 10174, March 2, 2005), Amendment 34 to the Crab FMP (76 FR 35772, June 20, 2011), Amendment 83 to the GOA FMP (76 FR 74670, December 1, 2011), and Amendment 45 to the Crab FMP (80 FR 28539, May 19, 2015). Also, NMFS published a final rule (84 FR 2723, February 8, 2019) that implemented regulations to prohibit non-AFA crab vessels from directed fishing for all groundfish species or species groups subject to sideboard limits, except for Pacific cod apportioned to CVs using pot gear in the Western and Central Regulatory Areas (§ 680.22(e)(1)(iii)). Accordingly, the GOA annual harvest specifications include only the non-AFA crab vessel groundfish sideboard limits for Pacific cod apportioned to CVs using pot gear in the Western and Central Regulatory Areas.

Table 16 lists the proposed 2023 and 2024 groundfish sideboard limits for non-AFA crab vessels. All targeted or incidental catch of sideboard species made by non-AFA crab vessels or associated LLP licenses will be deducted from these sideboard limits.

TABLE 16—PROPOSED 2023 AND 2024 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Season/gear	Area/component/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Proposed 2023 and 2024 TACs	Proposed 2023 and 2024 non-AFA crab vessel sideboard limit
Pacific cod	A Season, January 1–June 10.	Western Pot CV	0.0997	3,879	387
		Central Pot CV	0.0474	8,311	394
	B Season, September 1–December 31.	Western Pot CV	0.0997	2,210	220
		Central Pot CV	0.0474	4,651	220

Rockfish Program Groundfish Sideboard and Halibut PSC Limitations

The Rockfish Program establishes three classes of sideboard provisions: CV groundfish sideboard restrictions, CP rockfish sideboard restrictions, and CP opt-out vessel sideboard restrictions (§ 679.82(c)(1)). These sideboards are intended to limit the ability of rockfish harvesters to expand into other fisheries.

CVs participating in the Rockfish Program may not participate in directed fishing for dusky rockfish, Pacific ocean perch, and northern rockfish in the Western GOA and West Yakutat District from July 1 through July 31. Also, CVs may not participate in directed fishing for arrowtooth flounder, deep-water flatfish, and rex sole in the GOA from July 1 through July 31 (§ 679.82(d)).

Prior to 2021, CPs participating in Rockfish Program cooperatives were restricted by rockfish sideboard limits in the Western GOA. A final rule that implemented Amendment 111 to the FMP (86 FR 11895, March 1, 2021) removed Western GOA rockfish sideboard ratios for Rockfish Program CPs from regulation. That rule also revised and clarified the establishment of West Yakutat District rockfish sideboard ratios in regulation, rather than specifying the West Yakutat District rockfish sideboard ratios in the annual GOA harvest specifications.

CPs participating in Rockfish Program cooperatives are restricted by rockfish and halibut PSC sideboard limits. These CPs are prohibited from directed fishing for dusky rockfish, Pacific ocean perch, and northern rockfish in the Western GOA and West Yakutat District from July 1 through July 31 (§ 679.82(e)(2)). The sideboard ratio for each rockfish fishery in the West Yakutat District is set forth in § 679.82(e)(4). The rockfish sideboard ratio for each rockfish fishery in the West Yakutat District is an established percentage of the TAC for catcher/processors in the directed fishery for dusky rockfish and Pacific ocean perch. These percentages are confidential. Holders of CP-designated LLP licenses that opt out of participating in a Rockfish Program cooperative will be able to access that portion of each rockfish sideboard limits that is not assigned to Rockfish Program cooperatives (§ 679.82(e)(7)).

Under the Rockfish Program, the CP sector is subject to halibut PSC sideboard limits for the trawl deep-water and shallow-water species fisheries from July 1 through July 31 (§ 679.82(e)(3) and (5)). Halibut PSC sideboard ratios by fishery are set forth in § 679.82(e)(5). No halibut PSC sideboard limits apply to the CV sector, as vessels participating in a rockfish cooperative receive a portion of the annual halibut PSC limit. CPs that opt out of the Rockfish Program would be able to access that portion of the deep-water and shallow-water halibut PSC sideboard limit not assigned to CP rockfish cooperatives. The sideboard provisions for CPs that elect to opt out of participating in a rockfish cooperative are described in § 679.82(c), (e), and (f). Sideboard limits are linked to the catch history of specific vessels that may choose to opt out. After March 1, NMFS will determine which CPs have opted-out of the Rockfish Program in 2023, and will know the ratios and amounts used to calculate opt-out sideboard ratios. NMFS will then calculate any applicable opt-out sideboard limits for 2023 and post these limits on the Alaska

Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports#central-goa-rockfish.* Table 17 lists the proposed 2023 and 2024 Rockfish Program halibut PSC sideboard limits for the CP sector.

TABLE 17—PROPOSED 2023 AND 2024 ROCKFISH PROGRAM HALIBUT PSC SIDEBOARD LIMITS FOR THE CATCHER/PROCESSOR SECTOR

[Values are rounded to the nearest metric ton]

Sector	Shallow-water species fishery halibut PSC sideboard ratio (percent)	Deep-water species fishery halibut PSC sideboard ratio (percent)	Annual halibut PSC limit (mt)	Annual shallow-water species fishery halibut PSC sideboard limit (mt)	Annual deep-water species fishery halibut PSC sideboard limit (mt)
Catcher/processor	0.10	2.50	1,705	2	43

Amendment 80 Program Groundfish and PSC Sideboard Limits

Amendment 80 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (Amendment 80 Program) established a limited access privilege program for the non-AFA trawl CP sector. The Amendment 80 Program established groundfish and halibut PSC limits for Amendment 80 Program participants to limit the ability of participants eligible for the Amendment 80 Program to expand their harvest efforts in the GOA.

Section 679.92 establishes groundfish harvesting sideboard limits on all Amendment 80 Program vessels, other than the F/V *Golden Fleece,* to amounts no greater than the limits shown in Table 37 to 50 CFR part 679. Under § 679.92(d), the F/V *Golden Fleece* is prohibited from directed fishing for pollock, Pacific cod, Pacific ocean perch, dusky rockfish, and northern rockfish in the GOA.

Groundfish sideboard limits for Amendment 80 Program vessels operating in the GOA are based on their average aggregate harvests from 1998 through 2004 (72 FR 52668, September 14, 2007). Table 18 lists the proposed 2023 and 2024 groundfish sideboard limits for Amendment 80 Program vessels. NMFS will deduct all targeted or incidental catch of sideboard species made by Amendment 80 Program vessels from the sideboard limits in Table 18.

TABLE 18—PROPOSED 2023 AND 2024 GOA GROUNDFISH SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS

[Values are rounded to the nearest metric ton]

Species	Season	Area	Ratio of Amendment 80 sector vessels 1998–2004 catch to TAC	Proposed 2023 and 2024 TAC (mt) [3]	Proposed 2023 and 2024 Amendment 80 vessel sideboard limits (mt)
Pollock	A Season, January 20–May 31.	Shumagin (610)	0.003	1,122	3
		Chirikof (620)	0.002	51,845	104
		Kodiak (630)	0.002	8,009	16
	B Season, September 1–November 1.	Shumagin (610)	0.003	22,384	67
		Chirikof (620)	0.002	16,797	34
		Kodiak (630)	0.002	21,795	44
	Annual	WYK (640)	0.002	6,663	13
Pacific cod	A Season [1], January 1–June 10.	W	0.020	3,879	78
		C	0.044	8,311	366
	B Season [2], September 1–December 31.	W	0.020	2,210	44
		C	0.044	4,651	205
	Annual	WYK	0.034	2,045	70
Pacific ocean perch	Annual	W	0.994	2,523	2,508
		WYK	0.961	1,366	1,313
Northern rockfish	Annual	W	1.000	1,859	1,859
Dusky rockfish	Annual	W	0.764	259	198
		WYK	0.896	412	369

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.
[3] The Western and Central GOA and WYK District area apportionments of pollock are considered ACLs.

The halibut PSC sideboard limits for Amendment 80 Program vessels in the GOA are based on the historical use of halibut PSC by Amendment 80 Program vessels in each PSC target category from 1998 through 2004. These values are slightly lower than the average historical use to accommodate two factors: allocation of halibut PSC cooperative quota under the Rockfish Program and the exemption of the F/V *Golden Fleece* from this restriction (§ 679.92(b)(2)). Table 19 lists the proposed 2023 and 2024 halibut PSC sideboard limits for Amendment 80

Program vessels. This table incorporates the maximum percentages of the halibut PSC sideboard limits that may be used by Amendment 80 Program vessels as contained in Table 38 to 50 CFR part 679. Any residual amount of a seasonal Amendment 80 halibut PSC sideboard limit may carry forward to the next season limit (§ 679.92(b)(2)).

TABLE 19—PROPOSED 2023 AND 2024 HALIBUT PSC SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS IN THE GOA

[Values are rounded to the nearest metric ton]

Season	Season dates	Fishery category	Historic Amendment 80 use of the annual halibut PSC limit (ratio)	Proposed 2023 and 2024 annual PSC limit (mt)	Proposed 2023 and 2024 Amendment 80 vessel PSC sideboard limit (mt)
1	January 20–April 1	shallow-water	0.0048	1,705	8
		deep-water	0.0115	1,705	20
2	April 1–July 1	shallow-water	0.0189	1,705	32
		deep-water	0.1072	1,705	183
3	July 1–August 1	shallow-water	0.0146	1,705	25
		deep-water	0.0521	1,705	89
4	August 1–October 1	shallow-water	0.0074	1,705	13
		deep-water	0.0014	1,705	2
5	October 1–December 31	shallow-water	0.0227	1,705	39
		deep-water	0.0371	1,705	63
Annual		Total shallow-water			117
	Total deep-water			357	
	Grand Total, all seasons and categories			474	

Classification

NMFS is issuing this proposed rule pursuant to section 305(d) of the Magnuson-Stevens Act. Through previous actions, the FMP and regulations are designed to authorize NMFS to take this action. See 50 CFR part 679. The NMFS Assistant Administrator has determined that the proposed harvest specifications are consistent with the FMP and preliminarily determined that the proposed harvest specifications are consistent with the Magnuson-Stevens Act and other applicable laws, subject to further review after public comment.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Order 12866.

NMFS prepared an EIS for the Alaska groundfish harvest specifications and alternative harvest strategies (see **ADDRESSES**) and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the ROD for the Final EIS. A SIR is being prepared for the final 2023 and 2024 harvest specifications to provide a subsequent assessment of the action and to address the need to prepare a Supplemental EIS (40 CFR 1501.11(b); 1502.9(d)(1)). Copies of the Final EIS, ROD, and annual SIRs for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental, social, and economic consequences of the proposed groundfish harvest specifications and alternative harvest strategies on resources in the action area. Based on the analysis in the Final EIS, NMFS concluded that the preferred Alternative (Alternative 2) provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information.

Initial Regulatory Flexibility Analysis

This Initial Regulatory Flexibility Analysis (IRFA) was prepared for this proposed rule, as required by Section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), to describe the economic impact that this proposed rule, if adopted, would have on small entities. The IRFA describes the action; the reasons why this proposed rule is proposed; the objectives and legal basis for this proposed rule; the estimated number and description of directly regulated small entities to which this proposed rule would apply; the recordkeeping, reporting, and other compliance requirements of this proposed rule; and the relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule. The IRFA also describes significant alternatives to this proposed rule that would accomplish the stated objectives of the Magnuson-Stevens Act, and any other applicable statutes, and that would minimize any significant economic impact of this proposed rule on small entities. The description of the proposed action, its purpose, and the legal basis are explained earlier in the preamble and are not repeated here.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. A shoreside processor primarily involved in seafood processing (NAICS code 311710) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual employment, counting all individuals employed on a full-time, part-time, or other basis, not in excess of 750 employees for all its affiliated operations worldwide.

Number and Description of Small Entities Regulated by This Proposed Rule

The entities directly regulated by the groundfish harvest specifications include: (a) entities operating vessels with groundfish Federal fisheries permits (FFPs) catching FMP groundfish in Federal waters (including those receiving direction allocations of groundfish); (b) all entities operating vessels, regardless of whether they hold groundfish FFPs, catching FMP groundfish in the State-waters parallel fisheries; and (c) all entities operating vessels fishing for halibut inside 3 miles of the shore (whether or not they have FFPs).

In 2021 (the most recent year of complete data), there were 671 individual CVs and CPs with gross revenues less than or equal to $11 million. This represents the potential suite of directly regulated small entities. This includes an estimated 668 small CV and 3 small CP entities in the GOA groundfish sector. The determination of entity size is based on vessel revenues and affiliated group revenues. This determination also includes an assessment of fisheries cooperative affiliations, although actual vessel ownership affiliations have not been completely established. However, the estimate of these 671 CVs and CPs may be an overstatement of the number of small entities. The CVs had average gross revenues that varied by gear type. Average gross revenues for hook-and-line CVs, pot gear CVs, and trawl gear CVs are estimated to be $390,000, $720,000, and $1.96 million, respectively. Average gross revenues for CP entities are confidential.

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

The action under consideration is the proposed 2023 and 2024 harvest specifications, apportionments, and Pacific halibut prohibited species catch limits for the groundfish fishery of the GOA. This action is necessary to establish harvest limits for groundfish during the 2023 and 2024 fishing years and is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act. The establishment of the proposed harvest specifications is governed by the Council's harvest strategy to govern the catch of groundfish in the GOA. This strategy was selected from among five alternatives, with the preferred alternative harvest strategy being one in which the TACs fall within the range of ABCs recommended by the SSC. Under the preferred harvest strategy, TACs are set to a level that falls within the range of ABCs recommended by the SSC; the sum of the TACs must achieve the OY specified in the FMP. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant.

The TACs associated with preferred harvest strategy are those recommended by the Council in October 2022. OFLs and ABCs for the species were based on recommendations prepared by the Council's Plan Team in September 2022, and reviewed by the Council's SSC in October 2022. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations. The TACs in these proposed 2023 and 2024 harvest specifications are unchanged from the 2023 TACs in the final 2022 and 2023 harvest specifications (87 FR 11599; March 2, 2022), and the sum of all TACs remains within the OY for the GOA.

The proposed 2023 and 2024 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods to calculate stock biomass. The proposed 2023 and 2024 TACs are based on the best available biological and socioeconomic information. The proposed 2023 and 2024 OFLs, ABCs, and TACs are consistent with the biological condition of groundfish stocks as described in the 2021 SAFE report, which is the most recent, completed SAFE report.

Under this action, the proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. The proposed TACs are within the range of proposed ABCs recommended by the SSC and do not exceed the biological limits recommended by the SSC (the ABCs and overfishing levels). For most species and species groups in the GOA, the Council recommended, and NMFS proposes, TACs equal to proposed ABCs, which is intended to maximize harvest opportunities in the GOA.

For some species and species groups, however, the Council recommended, and NMFS proposes, TACs that are less than the proposed ABCs, including for pollock in the W/C/WYK Regulatory Area, Pacific cod, shallow-water flatfish in the Western Regulatory Area, arrowtooth flounder in the Western Regulatory Area and SEO District, flathead sole in the Western and Central Regulatory Areas, other rockfish in the SEO District, and Atka mackerel. In the GOA, increasing TACs for some species may not result in increased harvest opportunities for those species. This is due to a variety of reasons. There may be a lack of commercial or market interest in some species. Additionally, there are fixed, and therefore constraining, PSC limits associated with the harvest of the GOA groundfish species that can lead to an underharvest of flatfish TACs. For this reason, the shallow-water flatfish, arrowtooth flounder, and flathead sole TACs are set to allow for increased harvest opportunities for these target species while conserving the halibut PSC limit for use in other fisheries. The other rockfish and Atka mackerel TACs are set to accommodate ICAs in other fisheries. Finally, the TACs for two species (pollock and Pacific cod) cannot be set equal to ABC, as the TAC must be reduced to account for the State's GHLs in these fisheries. The W/C/WYK Regulatory Area pollock TAC and the GOA Pacific cod TACs are therefore set to account for the State's GHLs for the State waters pollock and Pacific cod fisheries so that the ABCs are not exceeded. For most species in the GOA, the Council recommended, and NMFS proposes, that proposed TACs equal proposed ABCs, unless other conservation or management reasons support proposed TAC amounts less than the proposed ABCs.

Based upon the best available scientific data, and in consideration of the Council's objectives of this action, it appears that there are no significant alternatives to the proposed rule that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the proposed rule on small entities. This action is economically beneficial to entities operating in the GOA, including small entities. The action proposes TACs for commercially valuable species in the GOA and allows for the continued prosecution of the fishery, thereby creating the opportunity for fishery revenue. After public process, during which the Council solicited input from stakeholders, the Council concluded that the proposed harvest specifications would best accomplish the stated objectives articulated in the preamble for this proposed rule, and in applicable statutes, and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

This action does not modify recordkeeping or reporting requirements, or duplicate, overlap, or conflict with any Federal rules.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

Adverse impacts on marine mammals or endangered or threatened species resulting from fishing activities conducted under these harvest specifications are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: November 23, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2022–26173 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 231
Friday, December 2, 2022

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.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Iowa Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Iowa Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a meeting on Tuesday, December 6, 2022 at 2:00 p.m.–3:30 p.m. Central Time. The purpose of the meeting is to vote on report focused on employment discrimination and administrative closures.

DATES: The meeting will take place on Tuesday, December 6, 2022, from 2:00 p.m. –3:30 p.m. Central Time.

Online Registration (Audio/Visual): https://tinyurl.com/IASAC120622

Telephone (Audio Only): Dial 833- 435–1820 USA Toll Free; Access code: 160 755 9318

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, DFO, at *afortes@usccr.gov* or 202–681–0857.

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions. Committee meetings are available to the public through the above call in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over landline connections to the toll-free telephone number. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Iowa 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 Unit at the above email or street address.

Agenda

I. Welcome, Roll Call, and Announcements
II. Review Report
III. Public Comment
IV. Vote on Report
V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given fewer than 15 calendar days prior to the meeting because of the exceptional circumstances of pending expiration of Committee member appointment terms.

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26293 Filed 12–1–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the West Virginia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of web briefing.

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 West Virginia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public briefing via Zoom on Tuesday, December 13, 2022, at 2 p.m. Eastern Time. The purpose of the briefing is to hear testimony on disparate school discipline policies and practices in West Virginia public schools.

DATES: Tuesday, December 13, 2022, at 2 p.m. Eastern Time

Meeting Link (Audio/Visual): https://tinyurl.com/4bvrwvsu

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 161 989 1726

FOR FURTHER INFORMATION CONTACT: Ivy Davis, DFO, at *idavis@usccr.gov.*

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *idavis@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to *idavis@usccr.gov.* Persons who desire additional information may contact Sarah Villanueva, Support Specialist, at (260) 800–4892.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the

Commission on Civil Rights, West Virginia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or contact the DFO at: *idavis@usccr.gov* or the Support Specialist, at (260) 800–4892.

Agenda

I. Welcome and Roll Call
II. Opening Remarks
III. Panelist Testimony
IV. Committee Q&A
V. Public Comments
VI. Closing Remarks
VII. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26289 Filed 12–1–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business 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 (FACA) that the Arizona Advisory Committee (Committee) to the Commission will hold a series of virtual business meetings via ZoomGov on the following dates and times listed. The purpose of these meetings is to determine potential panelist invitees for upcoming briefings and panel briefing planning.

DATES: These meetings will take place on:

- Friday, January 6, 2023, from 11:00 a.m.–1:30 p.m. Arizona Time
- Friday, February 3, 2023, from 11:00 a.m.–1:30 p.m. Arizona Time
- Friday, March 3, 2023, from 11:00 a.m.–1:30 p.m. Arizona Time
- Friday, April 7, 2023, from 11:00 a.m.–1:30 p.m. Arizona Time

Access Information:

Link to Join (Audio/Visual) https://tinyurl.com/mr2cycdf

Telephone (Audio Only) Dial: 1–833–568–8864 (US Toll-free); Meeting ID: 161 809 7593#

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Kayla Fajota (DFO) at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.*

Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Announcements and Updates
III. Approval of Minutes
IV. Planning Meeting: Racial and Ethnic Disparities in Pediatric Healthcare
V. Public Comment
VI. Next Steps
VII. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26295 Filed 12–1–22; 8:45 am]

BILLING CODE P

CIVIL RIGHTS COMMISSION

Notice of Public Meeting of the Kentucky Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Kentucky Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a business meeting on Wednesday, December 14, 2022, at 12 p.m. (ET). The purpose of the meeting is to identify potential speakers for a series of briefings on Civil Asset Forfeiture in Kentucky.

DATES: The meeting will take place on Wednesday, December 14, 2022, at 12 p.m. (ET).

Meeting Link (Audio/Visual): https://tinyurl.com/26ndpyd8

Telephone (Audio Only): Dial 1–833–435–1820 USA Toll Free; Meeting ID: 161 402 3300

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, DFO, at *ero@usccr.gov* or 1–202–529–8246.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *ero@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Sarah Villanueva at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at 1–202–376–7533.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Kentucky 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 the above email or street address.

Agenda

I. Welcome and Roll Call
II. Discussion: Potential Speakers
III. Other Business
IV. Public Comment
V. Next Steps
VI. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26300 Filed 12–1–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Florida Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Florida Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Zoom at 3 p.m. ET on Monday, January 9, 2023, to review the testimony received concerning recent legislative changes to Florida's voting code.

DATES: The meeting will take place on Monday, January 9, 2023, from 3 p.m.–4 p.m. ET.

ADDRESSES:

Registration Link (Audio/Visual): https://tinyurl.com/2p8m7h47

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 160 727 7983

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 816–4158.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, members of the public who wish to speak during public comment must provide their name to the Commission; however, if a member of the public wishes to join anonymously, we ask that you please join by phone. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided. Individuals who would like to request additional accessibility accommodations, please email *mwojnaroski@usccr.gov* at least 10 business days prior to the 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 meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Florida 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 the above phone number.

Agenda

I. Welcome & Roll Call
II. Committee Discussion
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26297 Filed 12–1–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the North Carolina Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the North Carolina Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Zoom at 12 p.m. ET on Thursday, January 19, 2023, to discuss their report on Legal Financial Obligations in the state.

DATES: The meeting will take place on Thursday, January 19, 2023, from 12 p.m.–1:30 p.m. ET.

ADDRESSES:

Registration Link (Audio/Visual): https://tinyurl.com/5n6r6huj.

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 161 834 0416

FOR FURTHER INFORMATION CONTACT: Victoria Moreno, DFO, at *vmoreno@usccr.gov* or (434) 515–0204.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, members of the public who wish to speak during public comment must provide their name to the Commission; however, if a member of the public wishes to join anonymously, we ask that you please join by phone. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided for individuals who are deaf, deafblind, or hard of hearing. To request additional accommodations, please email *vmoreno@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, North Carolina 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 the above phone number.

Agenda

I. Welcome & Roll Call

II. Committee Discussion
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26288 Filed 12–1–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Georgia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via web conference on Wednesday, January 4, 2023, at 1:30 p.m. eastern time for the purpose of discussing post-report activities.

DATES: The meeting will take place on Wednesday, January 4, 2023, from 1:30 p.m.–2:30 p.m. ET.

ADDRESSES:

Register to Join (Audio/Visual): https://tinyurl.com/2hcyvbtc.

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 161 271 7128

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *svillanueva@usccr.gov* at least seven (7) business days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Sarah Villanueva at *svillanueva@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Georgia 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 the above phone number.

Agenda

I. Welcome and Roll Call
II. Approval of Minutes
III. Announcements and Updates
IV. Discussion: Post-Report Activities
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: November 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–26290 Filed 12–1–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–433–813]

Strontium Chromate From Austria: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that strontium chromate from Austria produced and/or exported by Habich GmbH (Habich) was not sold in the United States at less than normal value (NV) during the period of review (POR) of November 1, 2020, through October 31, 2021.

DATES: Applicable December 2, 2022.

FOR FURTHER INFORMATION CONTACT: Jaron Moore or Brian Smith, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3640 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 27, 2019, Commerce published the antidumping duty order on strontium chromate from Austria.[1] On December 28, 2021, in accordance with 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the *Order,* covering one company, Habich.[2]

On July 19, 2022, we extended the deadline for the preliminary results of this review until November 30, 2022.[3] For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise covered by the *Order* is strontium chromate from Austria. The merchandise subject to review is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 2841.50.9100. Subject merchandise may also enter under HTSUS subheading 3212.90.0050. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1) and (2) of the Tariff Act of 1930, as amended (the Act). Constructed export price and export price were calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an

[1] *See Strontium Chromate from Austria and France: Antidumping Duty Orders,* 84 FR 65349 (November 27, 2019) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 73734 (December 28, 2021).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of 2020–2021 Antidumping Duty Administrative Review,'' dated July 19, 2022.

[4] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Strontium Chromate from Austria, 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period November 1, 2020, through October 31, 2021:

Producer and/or exporter	Weighted-average dumping margin (percent)
Habich GmbH	0.00 (*de minimis*).

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If Habich's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review and where Habich reported entered values, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). Where Habich has not reported entered values for all sales to a particular importer, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those transactions. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. Where either Habich's weighted-average dumping margin is zero or *de minimis* or an importer-specific assessment rate is zero or *de minimis,* we intend to instruct CBP to liquidate appropriate entries without regard to antidumping duties.'' [5]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Habich for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[6]

We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future cash deposits of estimated antidumping duties, where applicable.[7]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Habich will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis,* in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was examined; (3) if the exporter is not a firm covered in this review or another completed segment of this proceeding, but the producer is, the cash deposit rate will be the company-specific rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers and exporters will continue to be 25.90 percent, the all-others rate established in the less-than-fair-value investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[9] Rebuttal briefs, the content of which is limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[10] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via Commerce's electronic records system, ACCESS, within 30 days after the date of publication of this notice.[12] Requests should contain: (1) the party's name, address and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.[13] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions to Commerce must be filed using ACCESS [14] and must be

[5] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012).

[6] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[7] *See* section 751(a)(2)(C) of the Act.

[8] *See Order.*

[9] See 19 CFR 351.309(c)(1)(ii).

[10] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'').

[11] *See* 19 CFR 351.309(c)(2) and (d)(2).

[12] *See* 19 CFR 351.310(c).

[13] *See* 19 CFR 351.310(d).

[14] *See* 19 CFR 351.303.

served on interested parties.[15] An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time on the date that the document is due. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[16]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any case or rebuttal briefs, no later than 120 days after the date of publication of this notice, unless this deadline is extended.[17]

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: November 25, 2022.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Currency Conversion
VI. Recommendation

[FR Doc. 2022–26245 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–DS–P

[15] *See* 19 CFR 351.303(f).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID 19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[17] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h)(1).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–146]

Certain Freight Rail Couplers and Parts Thereof From the People's Republic of China: Postponement of Preliminary Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable December 2, 2022.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova or Paul Gill, AD/CVD Operations Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1280 or (202) 482–5673, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 18, 2022, the U.S. Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of certain freight rail couplers and parts thereof from the People's Republic of China.[1] Currently, the preliminary determination is due no later than December 22, 2022.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny it.

On November 21, 2022, the Coalition of Freight Coupler Producers (the petitioner) timely filed a request for Commerce to postpone the preliminary CVD determination so that Commerce may review all questionnaire responses and new factual information to permit a thorough investigation and the calculation of accurate subsidy rates.[2]

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than the next business day after 130 days after the date on which this investigation was initiated, *i.e.,* February 27, 2023.[3] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: November 28, 2022.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–26242 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Freight Rail Couplers and Parts Thereof from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 87 FR 64440 (October 25, 2022).

[2] *See* Petitioner's Letter, ''Request to Postpone Preliminary CVD Determination,'' dated November 21, 2022. The petitioner is the Coalition of Freight Coupler Producers, the members of which are McConway & Torley LLC and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union.

[3] The extended date for the preliminary determination falls on February 25, 2023, which is a Saturday. Commerce's practice dictates that, when a deadline falls on a weekend or Federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) received scope

ruling applications, requesting that scope inquiries be conducted to determine whether identified products are covered by the scope of antidumping duty (AD) and/or countervailing duty (CVD) orders and that Commerce issue scope rulings pursuant to those inquiries. In accordance with Commerce's regulations, we are notifying the public of the filing of the scope ruling applications listed below in the month of October 2022.

DATES: Applicable December 2, 2022.

FOR FURTHER INFORMATION CONTACT: Terri Monroe, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–1384.

Notice of Scope Ruling Applications

In accordance with 19 CFR 351.225(d)(3), we are notifying the public of the following scope ruling applications related to AD and CVD orders and findings filed in or around the month of October 2022. This notification includes, for each scope application: (1) identification of the AD and/or CVD orders at issue (19 CFR 351.225(c)(1)); (2) concise public descriptions of the products at issue, including the physical characteristics (including chemical, dimensional and technical characteristics) of the products (19 CFR 351.225(c)(2)(ii)); (3) the countries where the products are produced and the countries from where the products are exported (19 CFR 351.225(c)(2)(i)(B)); (4) the full names of the applicants; and (5) the dates that the scope applications were filed with Commerce and the name of the ACCESS scope segment where the scope applications can be found.[1] This notice does not include applications which have been rejected and not properly resubmitted. The scope ruling applications listed below are available on Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), at *https://access.trade.gov.*

Scope Ruling Applications

Standard Steel Welded Wire Mesh from Mexico (A–201–853/C–201–854); 6 x 6 W1.4/W1.4 or D1.4/D1.4 (*i.e.,* 10 gauge), 8′ x 131′ foot rolls of wire mesh (10 Gauge Wire Mesh); [2] produced in and exported from Mexico; submitted by Keysteel Corp.; Mid-South Wire Company; National Wire LLC; Oklahoma Steel & Wire Co.; and Wire Mesh Corp. (Domestic Producers); October 4, 2022; ACCESS scope segment ''10-Gauge Wire.''

Forged Steel Fittings from the People's Republic of China (China) (A–570–067/C–570–068); Forged Steel Fittings (FSF); [3] produced in and exported from China; submitted by UTEX Industries, Inc. (UTEX); October 10, 2022; ACCESS scope segment ''UTEX.''

Utility Scale Wind Towers from Spain, Germany, Denmark, the Netherlands, the United Kingdom, China (A–570–981, A–552–814, C–570–982, A–122–867, A–552–825, A–560–833, A–580–902, A–469–823, A–533–897, A–557–821, C–122–868, C–552–826, C–557–822, C–560–834, C–533–898); Monopiles; [4] produced in and exported from Spain, Germany, Denmark, the Netherlands, the United Kingdom, and China; submitted by Orsted North America Inc. (Orsted); October 10, 2022; ACCESS scope segment ''Monopile.''

Certain Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from China (A–570–979/C–570–980); Solar Modules; [5] produced in and exported from Cambodia; submitted by Sonali Energees USA LLC (Sonali); October 31, 2022; ACCESS scope segment ''Sonali.''

Notification to Interested Parties

This list of scope ruling applications is not an identification of scope inquiries that have been initiated. In accordance with 19 CFR 351.225(d)(1), if Commerce has not rejected a scope ruling application nor initiated the scope inquiry within 30 days after the filing of the application, the application will be deemed accepted and a scope inquiry will be deemed initiated the following day—day 31.[6] Commerce's practice generally dictates that where a deadline falls on a weekend, Federal holiday, or other non-business day, the appropriate deadline is the next business day.[7] Accordingly, if the 30th day after the filing of the application falls on a non-business day, the next business day will be considered the ''updated'' 30th day, and if the application is not rejected or a scope inquiry initiated by or on that particular business day, the application will be deemed accepted and a scope inquiry will be deemed initiated on the next business day which follows the ''updated'' 30th day.[8]

In accordance with 19 CFR 351.225(m)(2), if there are companion AD and CVD orders covering the same merchandise from the same country of origin, the scope inquiry will be conducted on the record of the AD proceeding. Further, please note that pursuant to 19 CFR 351.225(m)(1), Commerce may either apply a scope ruling to all products from the same country with the same relevant physical characteristics, (including chemical, dimensional, and technical

[1] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300, 52316 (September 20, 2021) (*Final Rule*) (''It is our expectation that the **Federal Register** list will include, where appropriate, for each scope application the following data: (1) identification of the AD and/or CVD orders at issue; (2) a concise public summary of the product's description, including the physical characteristics (including chemical, dimensional and technical characteristics) of the product; (3) the country(ies) where the product is produced and the country from where the product is exported; (4) the full name of the applicant; and (5) the date that the scope application was filed with Commerce.'')

[2] The product covered by this scope application is standard steel welded reinforcement wire mesh comprised of square and rectangular grids of uniformly spaced steel wires, either smooth or deformed, that are welded at all intersections, in the following style: 6x6 W1.4/W1.4 or D1.4/D1/4 (*i.e.,* 10 gauge), in roll form with a nominal width of 8 feet and a nominal length of 131 feet. The 10-gauge wire mesh that is the subject of this scope is classifiable under HTSUS 7314.20.0000 and 7314.39.0000.

[3] UTEX fittings are custom forged fittings used in a specific system for the drilling and extraction of oil and natural gas. The fittings that are included in this scope application are used in UTEX's LargeBore system and include cross-box fittings, expansion spool fittings, flange adapter assembly, flange adapter fittings, collar fittings, threaded elbow fittings, union fittings and swivel fittings. The UTEX fittings subject to this scope application are classified under HTSUS 7307.92.3030, 7307.92.9000 and 7307.99.5060.

[4] Monopiles are hollow cylindrical shapes made from steel used to form a foundation on which a complete offshore wind turbine sits. the majority of modern monopiles range from 1, 000 to 2,500 tons. Monopiles are welded together at the fabrication point and shipped to the installation point in one piece ranging from 80 to 130 meters in length. Monopiles designed for use with a transition piece may be on average approximately 20 meters shorter. Monopiles are classified under HTSUS 7308.20.0020.

[5] Solar modules manufactured in Cambodia from solar cells manufactured in Cambodia using Chinese unfinished silicon wafers. The merchandise subject to this scope application is classified under HTSUS number 8541.43.00.

[6] In accordance with 19 CFR 351.225(d)(2), within 30 days after the filing of a scope ruling application, if Commerce determines that it intends to address the scope issue raised in the application in another segment of the proceeding (such as a circumvention inquiry under 19 CFR 351.226 or a covered merchandise inquiry under 19 CFR 351.227), it will notify the applicant that it will not initiate a scope inquiry, but will instead determine if the product is covered by the scope at issue in that alternative segment.

[7] *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[8] This structure maintains the intent of the applicable regulation, 19 CFR 351.225(d)(1), to allow day 30 and day 31 to be separate business days.

characteristics) as the product at issue, on a country-wide basis, regardless of the producer, exporter, or importer of those products, or on a company-specific basis.

For further information on procedures for filing information with Commerce through ACCESS and participating in scope inquiries, please refer to the Filing Instructions section of the Scope Ruling Application Guide, at *https://access.trade.gov/help/Scope_Ruling_Guidance.pdf.* Interested parties, apart from the scope ruling applicant, who wish to participate in a scope inquiry and be added to the public service list for that segment of the proceeding must file an entry of appearance in accordance with 19 CFR 351.103(d)(1) and 19 CFR 351.225(n)(4). Interested parties are advised to refer to the case segment in ACCESS as well as 19 CFR 351.225(f) for further information on the scope inquiry procedures, including the timelines for the submission of comments.

Please note that this notice of scope ruling applications filed in AD and CVD proceedings may be published before any potential initiation, or after the initiation, of a given scope inquiry based on a scope ruling application identified in this notice. Therefore, please refer to the case segment on ACCESS to determine whether a scope ruling application has been accepted or rejected and whether a scope inquiry has been initiated.

Interested parties who wish to be served scope ruling applications for a particular AD or CVD order may file a request to be included on the annual inquiry service list during the anniversary month of the publication of the AD or CVD order in accordance with 19 CFR 351.225(n) and Commerce's procedures.[9]

Interested parties are invited to comment on the completeness of this monthly list of scope ruling applications received by Commerce. Any comments should be submitted to James Maeder, Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to *CommerceCLU@trade.gov.*

This notice of scope ruling applications filed in AD and CVD proceedings is published in accordance with 19 CFR 351.225(d)(3).

[9] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021).

Dated: November 28, 2022.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2022–26243 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–835]

Stainless Steel Sheet and Strip in Coils From the Republic of Korea: Final Results of Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on stainless steel sheet and strip in coils (sheet and strip) from the Republic of Korea (Korea) would likely lead to the continuation or recurrence of a countervailable subsidy at the levels indicated in the ''Final Results of the Sunset Review'' section of this notice.

DATES: Applicable December 2, 2022.

FOR FURTHER INFORMATION CONTACT: John Hoffner, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3315.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2022, Commerce initiated this fourth sunset review of the CVD order [1] on sheet and strip from Korea, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] This sunset review covers the five-year period from 2017 to 2021. Commerce received a notice of intent to participate from Cleveland-Cliffs Inc., North American Stainless, and Outokumpu Stainless USA LLC (collectively, the domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i). The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as domestic producers of sheet and strip in the United States.

Commerce received an adequate substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). However, Commerce did not receive a substantive response from any government or respondent interested party to this proceeding.

On October 25, 2022, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[3] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The merchandise subject to the *Order* consists of stainless steel sheet and strip in coils from Korea. Stainless steel is alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.,* cold-rolled, polished, aluminized, coated, etc.) provided that it maintains the specific dimensions of sheet and strip following such processing.

The merchandise subject to the *Order* is classified in the Harmonized Tariff Schedule of the United States (HTS) at subheadings: 7219.13.00.30, 7219.13.00.50, 7219.13.00.70, 7219.13.00.80, 7219.14.00.30, 7219.14.00.65, 7219.14.00.90, 7219.32.00.05, 7219.32.00.20, 7219.32.00.25, 7219.32.00.35, 7219.32.00.36, 7219.32.00.38, 7219.32.00.42, 7219.32.00.44, 7219.33.00.05, 7219.33.00.20, 7219.33.00.25, 7219.33.00.35, 7219.33.00.36, 7219.33.00.38, 7219.33.00.42, 7219.33.00.44, 7219.34.00.05, 7219.34.00.20, 7219.34.00.25, 7219.34.00.30, 7219.34.00.35, 7219.35.00.05, 7219.35.00.15, 7219.35.00.30, 7219.35.00.35, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.12.10.00, 7220.12.50.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80,

[1] *See Amended Final Determination: Stainless Steel Sheet and Strip in Coils from the Republic of Korea;* and *Notice of Countervailing Duty Orders: Stainless Steel Sheet and Strip in Coils from France, Italy, and the Republic of Korea,* 64 FR 42923 (August 6, 1999) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 87 FR 53727 (September 1, 2022).

[3] *See* Commerce's Letter, ''Sunset Reviews Initiated on September 1, 2022,'' dated October 25, 2022.

7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.20.70.05, 7220.20.70.10, 7220.20.70.15, 7220.20.70.60, 7220.20.70.80, 7220.20.80.00, 7220.20.90.30, 7220.20.90.60, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, and 7220.90.00.80.

Although the HTS subheadings are provided for convenience and customs purposes, Commerce's written description of the merchandise subject to the *Order* is dispositive.

Excluded from the scope of the *Order* are the following: (1) sheet and strip that is not annealed or otherwise heat treated and pickled or otherwise descaled, (2) sheet and strip that is cut to length, (3) plate (*i.e.,* flat-rolled stainless steel products of a thickness of 4.75 mm or more), (4) flat wire (*i.e.,* cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm), and (5) razor blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. *See* Chapter 72 of the HTS, ''Additional U.S. Note'' 1(d).

In response to comments by interested parties, Commerce determined that certain specialty stainless steel products are also excluded from the scope of the *Order.* These excluded products are described below.

Flapper valve steel is defined as stainless steel strip in coils containing, by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves in compressors.

Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01 microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length.

Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of the *Order.* This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of less than 0.002 or greater than 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron.

Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of the *Order.* This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as ''Arnokrome III.'' [4]

Certain electrical resistance alloy steel is also excluded from the scope of the *Order.* This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials (ASTM) specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as ''Gilphy 36.'' [5]

Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of the *Order.* This high-strength, ductile stainless steel product is designated under the Unified Numbering System (UNS) as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as ''Durphynox 17.'' [6]

Finally, three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments are also excluded from the scope of the *Order.* These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.,* carpet knives).[7] This steel is similar to AISI grade 420 but containing, by weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as ''GIN4 Mo.'' The second excluded stainless steel strip in coils is similar to AISI 420–J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per 100 square microns. An example of this product is ''GIN5'' steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37

[4] ''Arnokrome III'' is a trademark of the Arnold Engineering Company.

[5] ''Gilphy 36'' is a trademark of Imphy, S.A.

[6] ''Durphynox 17'' is a trademark of Imphy, S.A.

[7] This list of uses is illustrative and provided for descriptive purposes only.

and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for example, ''GIN6.'' [8]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum, which is dated concurrently with and adopted by this notice.[9] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. Parties can find a complete discussion of all issues raised in this expedited sunset review and the corresponding recommendations in this public memorandum, which is on file electronically via the Enforcement and Compliance Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNotices/ListLayout.aspx.*

Final Results of the Sunset Review

Pursuant to sections 752(b)(1) and (3) of the Act, we determine that revocation of the *Order* on sheet and strip from Korea would be likely to lead to continuation or recurrence of a net countervailable subsidy at the rates listed below: [10]

Producer/exporter	Subsidy rate (percent *ad valorem*)
INI/BNG (formerly Inchon and now known as Hyundai)	0.54
DMC	0.67
Taihan	4.64
All Others	0.63

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218(e)(ii)(c)(2).

Dated: November 25, 2022.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–26244 Filed 12–1–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 84–33A12]

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to Northwest Fruit Exporters (''NFE''), application no. 84–33A12.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review (''Certificate'') to NFE on November 14, 2022.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Content

NFE's Certificate was amended as follows:

1. Added the following companies as new Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)) for the following Export Product: fresh sweet cherries:

- Chuy's Cherries LLC, Mattawa, WA
- Columbia Fresh Packing LLC, Kennewick, WA
- Lateral Roots Farm, LLC, Wapato, WA

2. Changed the names of the following Members:

- Chelan Fruit Cooperative (Chelan, WA) changed to Chelan Fruit (Chelan, WA)
- Manson Growers Cooperative (Manson, WA) changed to Manson Growers (Manson, WA)

3. Changed the location of the following Member:

- Stadelman Fruit, L.L.C. (Milton-Freewater, OR, and Zillah, WA) changed to Stadelman Fruit, L.L.C. (Milton-Freewater, OR, Hood River, OR, and Zillah, WA)

4. Changed the Export Product coverage for seven Members:

- Highland Fruit Growers, Inc. changed Export Product coverage from fresh apples to fresh apples and fresh sweet cherries (adding fresh sweet cherries)
- Piepel Premium Fruit Packing LLC changed Export Product coverage from fresh apples to fresh apples and fresh sweet cherries (adding fresh sweet cherries)
- Washington Fruit & Produce Co. changed Export Product coverage

[8] ''GIN4 Mo,'' ''GIN5,'' and ''GIN6'' are the proprietary grades of Hitachi Metals America, Ltd.

[9] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Expedited Sunset Review of the Countervailing Duty Order on Stainless Steel Sheet and Strip in Coils from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[10] *Id.*

from fresh apples to fresh apples and fresh sweet cherries (adding fresh sweet cherries)
- Blue Star Growers, Inc. changed Export Product coverage from fresh apples and fresh pears to fresh pears (dropping fresh apples)
- Stadelman Fruit, L.L.C. changed Export Product coverage from fresh apples, fresh sweet cherries, and fresh pears to fresh apples and fresh pears (dropping fresh sweet cherries)
- AltaFresh L.L.C. dba Chelan Fresh Marketing changed Export Product coverage from fresh apples to fresh apples and fresh sweet cherries (adding fresh sweet cherries)
- Congdon Packing Co. L.L.C. changed Export Product coverage from fresh apples, and fresh pears to fresh apples, fresh sweet cherries, and fresh pears (adding fresh sweet cherries)

NFE's amended Certificate Membership is as follows:

1. Allan Bros., Naches, WA
2. AltaFresh L.L.C. dba Chelan Fresh Marketing, Chelan, WA (for fresh apples and fresh sweet cherries)
3. Apple House Warehouse & Storage, Inc., Brewster, WA
4. Apple King, L.L.C., Yakima, WA
5. Auvil Fruit Co., Inc. dba Gee Whiz II, LLC, Orondo, WA
6. Baker Produce, Inc., Kennewick, WA
7. Blue Bird, Inc., Peshastin, WA
8. Blue Star Growers, Inc., Cashmere, WA (for fresh pears only)
9. Borton & Sons, Inc., Yakima, WA
10. Brewster Heights Packing & Orchards, LP, Brewster, WA
11. Chelan Fruit, Chelan, WA
12. Chiawana, Inc. dba Columbia Reach Pack, Yakima, WA
13. Chuy's Cherries LLC, Mattawa, WA (fresh sweet cherries)
14. CMI Orchards LLC, Wenatchee, WA
15. Columbia Fresh Packing LLC, Kennewick, WA (fresh sweet cherries)
16. Columbia Fruit Packers, Inc., Wenatchee, WA
17. Columbia Valley Fruit, L.L.C., Yakima, WA
18. Congdon Packing Co. L.L.C., Yakima, WA (for fresh apples, fresh sweet cherries, and fresh pears)
19. Cowiche Growers, Inc., Cowiche, WA
20. CPC International Apple Company, Tieton, WA
21. Crane & Crane, Inc., Brewster, WA
22. Custom Apple Packers, Inc., Quincy, and Wenatchee, WA
23. Diamond Fruit Growers, Inc., Odell, OR
24. Domex Superfresh Growers LLC, Yakima, WA
25. Douglas Fruit Company, Inc., Pasco, WA
26. Dovex Export Company, Wenatchee, WA
27. Duckwall Fruit, Odell, OR
28. E. Brown & Sons, Inc., Milton-Freewater, OR
29. Evans Fruit Co., Inc., Yakima, WA
30. E.W. Brandt & Sons, Inc., Parker, WA
31. FirstFruits Farms, LLC, Prescott, WA
32. Frosty Packing Co., LLC, Yakima, WA
33. G&G Orchards, Inc., Yakima, WA
34. Gilbert Orchards, Inc., Yakima, WA
35. Hansen Fruit & Cold Storage Co., Inc., Yakima, WA
36. Henggeler Packing Co., Inc., Fruitland, ID
37. Highland Fruit Growers, Inc., Yakima, WA (for fresh apples and fresh sweet cherries)
38. HoneyBear Growers LLC, Brewster, WA
39. Honey Bear Tree Fruit Co LLC, Wenatchee, WA
40. Hood River Cherry Company, Hood River, OR
41. JackAss Mt. Ranch, Pasco, WA
42. Jenks Bros Cold Storage & Packing, Royal City, WA
43. Kershaw Fruit & Cold Storage, Co., Yakima, WA
44. Lateral Roots Farm, LLC, Wapato, WA (fresh sweet cherries)
45. L & M Companies, Union Gap, WA
46. Legacy Fruit Packers LLC, Wapato, WA
47. Manson Growers, Manson, WA
48. Matson Fruit Company, Selah, WA
49. McDougall & Sons, Inc., Wenatchee, WA
50. Monson Fruit Co., Selah, WA
51. Morgan's of Washington dba Double Diamond Fruit, Quincy, WA
52. Northern Fruit Company, Inc., Wenatchee, WA
53. Olympic Fruit Co., Moxee, WA
54. Oneonta Trading Corp., Wenatchee, WA
55. Orchard View Farms, Inc., The Dalles, OR
56. Pacific Coast Cherry Packers, LLC, Yakima, WA
57. Piepel Premium Fruit Packing LLC, East Wenatchee, WA (for fresh apples and fresh sweet cherries)
58. Pine Canyon Growers LLC, Orondo, WA
59. Polehn Farms, Inc., The Dalles, OR
60. Price Cold Storage & Packing Co., Inc., Yakima, WA
61. Quincy Fresh Fruit Co., Quincy, WA
62. Rainier Fruit Company, Selah, WA
63. River Valley Fruit, LLC, Grandview, WA
64. Roche Fruit, Ltd., Yakima, WA
65. Sage Fruit Company, L.L.C., Yakima, WA
66. Smith & Nelson, Inc., Tonasket, WA
67. Stadelman Fruit, L.L.C., Milton-Freewater, OR, Hood River, OR, and Zillah, WA (for fresh apples and fresh pears only)
68. Stemilt Growers, LLC, Wenatchee, WA
69. Symms Fruit Ranch, Inc., Caldwell, ID
70. The Dalles Fruit Company, LLC, Dallesport, WA
71. Underwood Fruit & Warehouse Co., Bingen, WA
72. Valicoff Fruit Company Inc., Wapato, WA
73. Washington Cherry Growers, Peshastin, WA
74. Washington Fruit & Produce Co., Yakima, WA (for fresh apples and fresh sweet cherries)
75. Western Sweet Cherry Group, LLC, Yakima, WA
76. Whitby Farms, Inc. dba: Farm Boy Fruit Snacks LLC, Mesa, WA
77. WP Packing LLC, Wapato, WA
78. Yakima Fruit & Cold Storage Co., Yakima, WA
79. Zirkle Fruit Company, Selah, WA

The amended Certificate is effective from August 16, 2022, the date on which the application for the Certificate was deemed submitted.

Dated: November 28, 2022.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2022–26217 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–845, A–580–834, A–583–831]

Stainless Steel Sheet and Strip in Coils From Japan, the Republic of Korea, and Taiwan: Final Results of Expedited Fourth Sunset Reviews of Antidumping Duty Orders.

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these sunset reviews, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on stainless steel sheet and strip in coils (SSSSC) from Japan, the Republic of Korea (Korea), and Taiwan would be likely to lead to the continuation or recurrence of dumping at the dumping margins identified in the ''Final Results of Reviews'' section of this notice.

DATES: Applicable December 2, 2022.

FOR FURTHER INFORMATION CONTACT: Andrew Hart, AD/CVD Operations, Enforcement and Compliance,

International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1058.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2022, Commerce published the notice of initiation of the fourth sunset reviews of the AD orders on SSSSC from Japan, Korea, and Taiwan [1] pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On September 15, 2022, Cleveland-Cliffs Inc., North American Stainless, and Outokumpu Stainless USA, LLC (collectively, the domestic interested parties), notified Commerce of their intent to participate within the 15-day period specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as producers of the domestic like product in the United States.

On September 30, 2022, Commerce received complete substantive responses to the *Notice of Initiation* with respect to each of the *Orders* from the domestic interested parties within the 30-day period specified in 19 CFR 351.218(d)(3)(i).[4] Commerce received no substantive responses from respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset reviews of the *Orders.*

Scope of the Orders

The scope of the *Orders* is stainless steel sheet and strip in coils from Japan, Korea, and Taiwan. The merchandise subject to the *Orders* is classified in the Harmonized Tariff Schedule of the United States (HTS) at subheadings: 7219.13.00.31, 7219.13.00.51, 7219.13.00.71, 7219.13.00.81, 7219.14.00.30, 7219.14.00.65, 7219.14.00.90, 7219.32.00.05, 7219.32.00.20, 7219.32.00.25, 7219.32.00.35, 7219.32.00.36, 7219.32.00.38, 7219.32.00.42, 7219.32.00.44, 7219.33.00.05, 7219.33.00.20, 7219.33.00.25, 7219.33.00.35, 7219.33.00.36, 7219.33.00.38, 7219.33.00.42, 7219.33.00.44, 7219.34.00.05, 7219.34.00.20, 7219.34.00.25, 7219.34.00.30, 7219.34.00.35, 7219.35.00.05, 7219.35.00.15, 7219.35.00.30, 7219.35.00.35, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.12.10.00, 7220.12.50.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.20.70.05, 7220.20.70.10, 7220.20.70.15, 7220.20.70.60, 7220.20.70.80, 7220.20.80.00, 7220.20.90.30, 7220.20.90.60, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, and 7220.90.00.80. Although the HTS subheadings are provided for convenience and customs purposes, the written product description remains dispositive.

For a full description of the scope of the *Orders, see* the Issues and Decision Memorandum.[5]

Analysis of Comments Received

A complete discussion of all issues raised in these sunset reviews is provided in the Issues and Decision Memorandum, including the likelihood of the continuation or recurrence of dumping and the magnitude of the margins of dumping likely to prevail if the *Orders* were revoked. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *http://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of the Sunset Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Orders* would likely lead to the continuation or recurrence of dumping and that the magnitude of the dumping margins likely to prevail would be up to 57.87 percent for Japan, 58.79 percent for Korea, and 21.10 percent for Taiwan.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.221(c)(5)(ii).

Dated: November 23, 2022.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–26241 Filed 12–1–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Notice of Antidumping Duty Order: Stainless Steel Sheet and Strip in Coils from United Kingdom, Taiwan, and South Korea,* 64 FR 40555 (July 27, 1999); and *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Stainless Steel Sheet and Strip in Coils from Japan,* 64 FR 40565 (July 27, 1999) (collectively, *Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 87 FR 53727 (September 1, 2022) (*Notice of Initiation*).

[3] *See* Domestic Interested Parties' Letter, ''Domestic Interested Parties' Notice of Intent to Participate,'' dated September 15, 2022 (Japan); *see also* Domestic Interested Parties' Letter, ''Domestic Interested Parties' Notice of Intent to Participate,'' dated September 15, 2022 (Korea); and Domestic Interested Parties' Letter, ''Domestic Interested Parties' Notice of Intent to Participate,'' dated September 15, 2022 (Taiwan).

[4] *See* Domestic Interested Parties' Letter, ''Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 30, 2022 (Japan); *see also* Domestic Interested Parties' Letter, ''Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 30, 2022 (Korea); and Domestic Interested Parties' Letter, ''Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 30, 2022 (Taiwan).

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Fourth Sunset Reviews of the Antidumping Duty Orders on Stainless Steel Sheet and Strip in Coils from Japan, the Republic of Korea, and Taiwan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF DEFENSE

Office of the Secretary

Reserve Forces Policy Board (RFPB); Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), 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 RFPB will take place.

DATES: The RFPB will hold a closed meeting on Wednesday, December 7, 2022 from 8:30 a.m. to 4 p.m.

ADDRESSES: The RFPB meeting address is the Pentagon Gardner Room, Army Conference Center (3D684), Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Alexander Sabol, Designated Federal Officer (DFO), (703) 618–2470 (Voice), *Alexander.J.Sabol.Civ@Mail.Mil* (Email). Mailing address is Reserve Forces Policy Board, 5109 Leesburg Pike, Suite 501, Falls Church, VA 22041. The most up-to-date changes to the meeting agenda can be found on the website at *http://rfpb.defense.gov/.*

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the DFO, the RFPB was unable to provide public notification required by 41 CFR. 102–3.150(a) concerning its December 7, 2022 meeting Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR. 102–3.150(b), waives the 15-calendar day notification requirement. This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR. 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to obtain, review, and evaluate information related to strategies, policies, and practices designed to improve and enhance the capabilities, efficiency, and effectiveness of the Reserve Components.

Agenda: The RFPB will hold a closed meeting from 8:30 a.m. to 4 p.m., that will consist of remarks to the RFPB from following invited speakers: USD(P&R) will discuss his guidance on Reserve Component policies and his views on key challenges for the Reserve Component in supporting the Total Force programs in a contested Homeland; Deputy Assistant Secretary of Defense for Strategy and Force Development, Office of the Deputy Under Secretary of Defense for Strategy, Plans and Forces, Office of the Under Secretary of Defense for Policy will provide an overview of the National Defense Strategy focusing on Homeland Defense and Reserve Component roles in protecting critical infrastructure in a contested homeland; Assistant Secretary of Defense for Manpower & Reserve Affairs (ASD (M&RA)), Office of the Under Secretary of Defense for Personnel and Readiness will discuss guidance on ASD M&RA's priorities to include policies and programs involving the Reserve Component equipment, facilities and personnel readiness, and his views on key roles of the Reserve Component in a contested Homeland; Chair, Subcommittee for the Reserve Components' Role in Homeland Defense and Support to Civil Authorities Subcommittee will discuss the Subcommittee's focused priorities involving the Reserve Component Roles in Homeland Defense and support to civil authorities in defending the Nation's critical infrastructure; Cyber Mutual Assistance Program Electricity Subsector Coordinating Council Lead will discuss the electric power industry efforts to prepare for, and respond to, national-level disasters or threats to critical infrastructure and interagency coordination with the Federal Government and the Reserve Components; Chief, National Guard Bureau (CNGB) will discuss National Guard priorities in and challenges with defending the Homeland and use of the National Guard to support the defense of a contested Homeland and support to civil authorities; Deputy Assistant Secretary of Defense Cyber Policy, Office of the Assistant Secretary of Defense for Homeland Defense and Global Security, Office of the Under Secretary of Defense for Policy will discuss Cyber Policy's priorities in defending a contested Homeland and utilization of the Reserves and National Guard in Cyber operations; Assistant Secretary of Defense for Homeland Defense and Global Security, Office of the Under Secretary of Defense for Policy will discuss her guidance on Homeland Defense and Hemispheric Affairs priorities to include Reserve Components' policies and programs, and her views on key Reserve Component roles to support defense of a contested Homeland; the Homeland Combatant Commanders and CNGB's Panel will discuss priorities in defending the Homeland and use of the Reserves and National Guard to defend a contested Homeland, and will conclude with the Chairman who will process the day's discussion and determine where the Board can use its role to best provide support the taskings of the Secretary of Defense and the Sponsor, USD(P&R).

Meeting Accessibility: Pursuant to section 10(a)(1) of the FACA and 41 CFR 102–3.140 through 102–3.165, this meeting is closed to the public. In accordance with section 10(d) of the FACA, 5 U.S.C. 552b(c), and 41 CFR. 102–3.155, the DoD has determined that this meeting scheduled to occur from 8:30 a.m. to 4 p.m. will be closed to the public. Specifically, the USD(P&R), in coordination with the DoD FACA Attorney, has determined in writing that the meeting will be closed to the public because it is likely to disclose classified matters covered by 5 U.S.C. 552b(c)(1).

Written Statements: Pursuant to section 10(a)(3) of the FACA and 41 CFR. 102–3.105(j) and 102–3.140, interested persons may submit written statements to the RFPB about its approved agenda or at any time on the RFPB's mission. Written statements should be submitted to the RFPB's DFO at the address, email, or facsimile number listed in the **FOR FURTHER INFORMATION CONTACT** section. If statements pertain to a specific topic being discussed at the planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to or considered by the RFPB until its next meeting. The DFO will review all timely submitted written statements and provide copies to all the RFPB members before the meeting that is the subject of this notice. Please note that since the RFPB operates in accordance with the provisions of the FACA, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the RFPB's website.

Dated: November 29, 2022.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–26256 Filed 12–1–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0148]

Agency Information Collection Activities; Comment Request; Fiscal Operations Report for 2022–2023 and Application To Participate 2024–2025 (FISAP) and Reallocation Form

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 January 31, 2023.

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–2022–SCC–0148. 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* 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: Fiscal Operations Report for 2022–2023 and Application to Participate 2024–2025 (FISAP) and Reallocation Form.

OMB Control Number: 1845–0030.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 3,778.

Total Estimated Number of Annual Burden Hours: 88,626.

Abstract: The Higher Education Act of 1965, as amended, requires participating Title IV institutions to apply for funds and report expenditures for the Federal Perkins Loan (Perkins), the Federal Supplemental Educational Opportunity Grant (FSEOG) and the Federal Work-Study (FWS) Programs on an annual basis. The data submitted electronically in the Fiscal Operations Report and Application to Participate (FISAP) is used by the Department of Education to determine the institution's funding need for the award year and monitor program effectiveness and accountability of fund expenditures. The data is used in conjunction with institutional program reviews to assess the administrative capability and compliance of the applicant. There are no other resources for collecting this data.

Dated: November 28, 2022.

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. 2022–26222 Filed 12–1–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Future Release for the Administrative and Legal Requirements Document and Application Instructions for Formula Funding Under the Energy Efficiency and Conservation Block Grant Program

AGENCY: Office of State and Community Energy Programs, Department of Energy.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) Office of State and Community Energy Programs (SCEP) intends to issue an Administrative and Legal Requirements Document (ALRD) for the Energy Efficiency and Conservation Block Grant (EECBG) Program, as authorized by the Infrastructure Investment and Jobs Act (IIJA) of 2021. DOE has released a Notice of Intent (NOI) through the EECBG Program website so that interested parties are aware of SCEP's intention to issue an ALRD in the near term. All the information contained in the NOI is subject to change. In addition, the NOI provides information on the EECBG Program, including draft funding allocations to states, local governments, and Indian tribes and the potential option for formula grant recipients to select a voucher in lieu of a formula grant. The NOI provides additional details on eligibility requirements and information on submission and registration requirements for formula grant recipients.

ADDRESSES: Interested persons are encouraged to review the notice of intent to issue the ALRD on the EECBG Program website, *https://www.energy.gov/bil/energy-efficiency-and-conservation-block-grant-program.*

FOR FURTHER INFORMATION CONTACT: Mr. Adam Guzzo, U.S. Department of Energy, Office of State and Community Energy Programs, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1585. Email: *eecbg@hq.doe.gov*. Electronic communications are recommended for correspondence.

SUPPLEMENTARY INFORMATION: The EECBG Program provides federal grants to states, units of local government, and Indian tribes to assist eligible entities in implementing strategies to reduce fossil fuel emissions, to reduce total energy use, and to improve energy efficiency. The EECBG Program was authorized in title V, subtitle E of the Energy Independence and Security Act of 2007, and signed into law (Pub. L. 110–140) on December 19, 2007.

Through section 40552(b) of the IIJA, Public Law 117–58,[1] Congress authorized $550 million to the EECBG Program for Fiscal Year 2022, to remain available until expended. Of the $550 million IIJA appropriates for the EECBG Program, DOE intends to distribute $440 million in formula and competitive EECBG Program grants to eligible units of local government, states, and Indian tribes. The estimated amounts available for formula grants are as follows:

[1] *https://www.govinfo.gov/content/pkg/PLAW-117publ58/pdf/PLAW-117publ58.pdf.*

- $299,200,000 for formula grants to eligible units of local government
  - $149,600,000 to eligible units of local government- Alternative 1
  - $149,600,000 to eligible units of local government- Alternative 2
- $123,200,000 for formula grants to states
  - Each state (except for those noted as exempt on page 14 of the NOI) is required to pass not less than 60 percent of its allocation through to cities and counties within the state that are ineligible for direct formula grants from DOE
- $8,800,000 for formula grants to eligible Indian tribes

DOE has released a NOI through the EECBG Program website so that interested parties are aware of SCEP's intention to issue an ALRD in January 2023. All the information contained in the NOI is subject to change. Please see attachments 1a., 1b., and 1c. included with the NOI to preview the draft EECBG Program formula funding allocations for each of the 2,708 State, local, and Tribal governments that are eligible entities for EECBG Program formula grants.

Signing Authority

This document of the Department of Energy was signed on November 22, 2022, by Henry McKoy, Director of the Office of State and Community Energy Programs, 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 November 29, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–26279 Filed 12–1–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[EERE–2022–BT–STD–0026]

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings of the Commercial Unitary Air Conditioner and Commercial Unitary Heat Pump Working Group

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice of open meetings.

SUMMARY: The U.S. Department of Energy (DOE or the Department) announces two additional open meetings of the Commercial Unitary Air Conditioner and Commercial Unitary Heat Pump (CUAC and CUHP) working group. The Federal Advisory Committee Act (FACA) requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: December 7, 2022, from 10:00 a.m. to 5:00 p.m. via webinar; December 8, 2022, from 9:00 a.m. to 3:00 p.m. via webinar.

ADDRESSES: Meetings will be held virtually via Webex. See the Public Participation section of this notice for webinar registration information, participant instructions, and information about the capabilities available to webinar participants, or visit the committee's website at: *https://www.energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: Mr. Lucas Aiden, U.S. Department of Energy, Office of Building Technologies (EE–5B), 950 L'Enfant Plaza SW, Washington, DC 20024. Telephone: (202) 287–5904. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On July 21, 2022, the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) met and passed the recommendation to form a CUAC and CUHP working group to meet and discuss and, if possible, reach a consensus on proposed Federal test procedures and energy conservation standards for CUACs and CUHPs. On July 29, 2022, DOE published a notice of intent to establish a working group for CUACs and CUHPs to negotiate a notice of proposed rulemaking for test procedures and energy conservations standards. 87 FR 45703. On October 7, 2022, DOE published a notice announcing open meetings for the CUAC and CUHP working group. 87 FR 60942. This notice maintains that list of meetings and announces an additional two meetings in early December.

Purpose of Meetings: To provide advice and recommendations to ASRAC on test procedures and energy conservation standards for CUAC and CUHP equipment under the authority of the Negotiated Rulemaking Act (5 U.S.C. 561–570, Pub. L. 104–320).

Public Participation: Open meetings will be held via webinar on: Wednesday, December 7, 2022, from 10 a.m. to 5 p.m. EDT; and Thursday, December 8, 2022, from 9 a.m. to 3 p.m. EDT. To attend the webinars and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. The webinar will be held using the Webex software platform and participants are responsible for ensuring their systems are compatible with the webinar software. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *https://www.energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.*

Please note that foreign nationals participating in the webinar are subject to advance security screening procedures which require advance notice prior to attendance at the webinar. If a foreign national wishes to participate in the webinar, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

Members of the public will be heard in the order in which they sign up for the Public Comment Period. Time allotted per speaker will depend on the number of individuals who wish to speak but will not exceed five minutes. Reasonable provision will be made to include the scheduled oral statements on the agenda. A third-party neutral facilitator will make every effort to allow the presentations of views of all interested parties and to facilitate the orderly conduct of business.

Participation in the meetings is not a prerequisite for submission of written comments. Written comments are welcome from all interested parties. Any comments submitted must identify the CUAC and CUHP Working Group, and provide docket number EERE–2022–BT–STD–0015. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: CommPkgACHP2022STDandTP0015@ee.doe.gov.* Include docket number EERE–2022–BT–STD–0015 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (faxes) will be accepted.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *www.regulations.gov/docket/EERE-2022-BT-STD-0015.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of notice of open meetings.

Signing Authority

This document of the Department of Energy was signed on November 22, 2022, by Francisco Alejandro Moreno, Acting 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 November 28, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–26239 Filed 12–1–22; 8:45 am]

BILLING CODE 6450–01–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: PR23–10–000.

Applicants: Columbia Gas of Ohio, Inc.

Description: § 284.123 Rate Filing: COH Rates SOC Effective 10–27–2022 to be effective 10/27/2022.

Filed Date: 11/28/22.

Accession Number: 20221128–5040.

Comment Date: 5 p.m. ET 12/19/22.

Docket Numbers: RP23–207–000.

Applicants: MoGas Pipeline LLC.

Description: § 4(d) Rate Filing: MoGas Pipeline LLC Omega NRA Filing to be effective 1/1/2023.

Filed Date: 11/28/22.

Accession Number: 20221128–5012.

Comment Date: 5 p.m. ET 12/7/22.

Docket Numbers: RP23–208–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: CIG Qtly LUF True-up Nov 2022 to be effective 1/1/2023.

Filed Date: 11/28/22.

Accession Number: 20221128–5020.

Comment Date: 5 p.m. ET 12/7/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–26262 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at North American Electric Reliability Corporation Reliability and Security Technical Committee Meetings

The Federal Energy Regulatory Commission hereby gives notice that members of the Commission staff may attend the following meetings:

North American Electric Reliability Corporation Reliability and Security Technical Committee Virtual Meetings on:

December 6 (11 a.m.–4:30 p.m. eastern time) and December 7 (11 a.m.–4:30 p.m. eastern time), 2022

Further information regarding these meetings may be found at: *http://www.nerc.com/Pages/Calendar.aspx.*

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceeding:

Docket No. RD22–4–000 Registration of Inverter-Based Resources

For further information, please contact Jonathan First, 202–502–8529, or *jonathan.first@ferc.gov.*

Dated: November 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–26264 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP23–15–000; PF22–5–000]

ANR Pipeline Company; Notice of Application and Establishing Intervention Deadline

Take notice that on November 14, 2022, ANR Pipeline Company, LLC (ANR), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed an application under sections 7(b) and 7(c) of the Natural Gas Act (NGA), and Part

157 of the Commission's regulations requesting authorization to construct and operate its Wisconsin Reliability Project (WRP or Project), a reliability and expansion project located in Manitowoc, Marathon, Merrill, Oconto, Outagamie, Portage, Sheboygan, Washington, Waupaca, and Winnebago Counties, Wisconsin, and McHenry County, Illinois. ANR estimates the cost for the project to be $757,606,203.

Specifically, ANR's proposed Project consists of (a) the replacement of approximately 48 miles of ANR's existing pipeline with approximately 51 miles of new larger-diameter pipeline, located mostly within ANR's existing right-of-way, (b) modification and replacement of compression facilities at two existing compressor stations, (c) modifications to six meter stations, and (d) the installation and removal of auxiliary facilities. The Project will upgrade existing pipeline and compression facilities with new, more modern pipeline and compression facilities that will provide safe and reliable natural gas transportation service to ANR's existing customers and provide 132,000 dekatherms per day (Dth/d) of incremental mainline capacity on ANR's pipeline system. The incremental capacity of 132,000 Dth/d created as part of the Project, in conjunction with the utilization of 12,000 Dth/d of existing reserved capacity, will provide much needed natural gas supply to residential, commercial, and industrial consumers in the states of Wisconsin and Illinois, while increasing the base system reliability, safety and the long-term integrity of ANR's system.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions concerning this application should be directed to David A. Alonzo, Manager of Project Authorizations, ANR Pipeline Company, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, by telephone at (832) 320–5477, or by email at *david_alonzo@tcenergy.com*.

On April 4, 2021 the Commission granted the Applicant's request to utilize the National Environmental Policy Act (NEPA) Pre-Filing Process and assigned Docket No. PF22–5–000 to staff activities involved in the Project. Now, as of the filing of the November 14, 2022 application, the Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP23–15–000 as noted in the caption of this Notice.

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are two ways to become involved in the Commission's review of this project: you can file comments on the project, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 19, 2022.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 19, 2022.

[1] 18 CFR (Code of Federal Regulations) 157.9.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number CP23–015–000 in your submission.

(1) 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;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. 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 ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address below. Your written comments must reference the Project docket number (CP23–015–000).

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*. Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, 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. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[2] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [3] and the regulations under the NGA [4] by the intervention deadline for the project, which is December 19, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. [For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene.] For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP23–015–000 in your submission.

(1) You may file your motion to intervene 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 ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/sites//files/2020-05/document-less-intervention.pdf;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP23–015–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (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 of Project Authorizations, ANR Pipeline Company, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, or at *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.

All timely, unopposed [5] motions to intervene are automatically granted by operation of Rule 214(c)(1).[6] 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.[7] 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.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all 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 *https://ferconline.ferc.gov/LogIn.aspx.*

Intervention Deadline: 5:00 p.m. Eastern Time on December 19, 2022.

Dated: November 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–26267 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

[2] 18 CFR 385.102(d).

[3] 18 CFR 385.214.

[4] 18 CFR 157.10.

[5] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[6] 18 CFR 385.214(c)(1).

[7] 18 CFR 385.214(b)(3) and (d)

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2195–196]

Portland General Electric Company; Notice of Application Accepted for Filing and 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:* Temporary variance from Project Operating Plan.

b. *Project No.:* 2195–196.

c. *Date Filed:* October 19, 2022, and supplemented on November 7, 2022

d. *Applicant:* Portland General Electric Company (licensee).

e. *Name of Project:* Clackamas River Hydroelectric Project.

f. *Location:* The project is located on the mainstem of the Clackamas River and the Oak Grove Fork of the Clackamas River, in Clackamas County, Oregon and occupies federal lands within the Mt. Hood National Forest managed by the U.S. Forest Service and a reservation of the U.S. Department of Interior's Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

h. *Applicant Contact:* Ms. Lindsay Smith, License Coordinator, Portland General Electric, 121 SW Salmon Street, Portland, Oregon 97204; (503) 630–8378; *Lindsay.Smith@pgn.com.*

i. *FERC Contact:* Joy Kurtz, (202) 502–6760, *joy.kurtz@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is December 28, 2022.

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: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include docket number P–2195–196. 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.

k. *Description of Request:* The licensee requests Commission approval for a variance from the Project Operating Plan (Plan) in order to accommodate testing of new Units 7 and 8 at the Faraday Powerhouse. The Plan, in part, requires the licensee to operate River Mill Dam to limit the hourly ramping rate to 10% or 100 cubic feet per second, whichever is greater, of the U.S. Geological Survey (USGS) Estacada gage for all river flows. The testing is required in order to commission both units and place them into operation. The testing process will last approximately 90 days and begin between February 1 and April 15, 2023. Testing will require the licensee to shift water between Faraday Lake and Estacada Lake as it passes various flows through the new units. In some cases, testing will require the licensee to cease generation immediately after passing high flows through the units. Given this, and the details of other testing procedures, the licensee requests to increase the hourly ramping rate at River Mill Dam from 10% to 20% and use generation data and spillway flow to calculate project outflow, versus the USGS Estacada gage required by the Plan. During testing, the licensee will focus on limiting downramping rates rather than attempting to match outflow to inflow, which is the case under typical operating conditions, in an effort to protect biological resources downstream of River Mill Dam.

l. *Locations of the Application:* 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 website at *http://www.ferc.gov/docs-filing/elibrary.asp.* 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. Agencies may obtain copies of the application directly from the applicant. At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll free, (866) 208–3676 or TTY, (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *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. 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.

o. *Filing and Service of Responsive Documents:* All filings 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 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. A copy of all other filings in reference to this application 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 385.2010.

Dated: November 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–26268 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC23–26–000.

Applicants: EdSan 1B Group 1 Edwards, LLC, EdSan 1B Group 1 Sanborn, LLC, EdSan 1B Group 2, LLC, EdSan 1B Group 3, LLC, Daylight I, LLC, Edwards Solar Line I, LLC, Sanborn Solar Line I, LLC, Axium ES Holdings LLC.

Description: Amendment to November 10, 2022, Joint Application for Authorization Under Section 203 of the Federal Power Act of EdSan 1B Group 1 Edwards, LLC, et al.

Filed Date: 11/25/22.

Accession Number: 20221125–5048.

Comment Date: 5 p.m. ET 12/27/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23–476–001,

Applicants: Great Pathfinder Wind, LLC.

Description: Tariff Amendment: Affidavit of Adrian Kimbrough to be effective 2/1/2023.

Filed Date: 11/28/22.

Accession Number: 20221128–5090.

Comment Date: 5 p.m. ET 12/19/22.

Docket Numbers: ER23–497–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6707; Queue No. AD1–152 to be effective 10/31/2022.

Filed Date: 11/28/22.

Accession Number: 20221128–5018.

Comment Date: 5 p.m. ET 12/19/22.

Docket Numbers: ER23–498–000.

Applicants: California Independent System Operator Corporation.

Description: Notice of Termination of Scheduling Coordinator Agreement with

Bia Capital Management LLC and Request for Waiver of Notice Requirement of California Independent System Operator Corporation.

Filed Date: 11/23/22.

Accession Number: 20221123–5232.

Comment Date: 5 p.m. ET 12/14/22.

Docket Numbers: ER23–499–000.

Applicants: Avista Corporation.

Description: § 205(d) Rate Filing: Avista Corp FERC Rate Schedule T1188 Extension to be effective 1/1/2023.

Filed Date: 11/28/22.

Accession Number: 20221128–5039.

Comment Date: 5 p.m. ET 12/19/22.

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 or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–26263 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–16–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 18, 2022, Columbia Gas Transmission, LLC (Columbia), 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 157.208 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act (NGA) and Transco's blanket certificate issued in Docket No. CP83–76–000. Columbia is requesting authorization to perform installations and modifications to enable the in-line inspection (ILI), or pigging, of its 20-inch-diameter Line D100 (D100 ILI Make Piggable Project), at various locations in Seneca, Sandusky, and Wood Counties, Ohio. The estimated cost for the project is approximately $31 million, 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. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to David A. Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, phone: 832–320–5477, email: *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 January 27, 2023. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is January 27, 2023. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is January 27, 2023. 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

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

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 January 27, 2023. 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 CP23–16–000 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''; or [6]

(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 CP23–16–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Kimberly D. Bose, 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: 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700 or *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 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.*

Dated: November 28, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–26266 Filed 12–1–22; 8:45 am]

BILLING CODE 6717–01–P

[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.

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–046]

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 November 18, 2022 10 a.m. EST Through November 28, 2022 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. 20220178, Draft, FHWA, AR, Walnut Ridge—Missouri State Line (Future I–57), Comment Period Ends: 01/17/2023, Contact: Randal Looney 501–324–6430.

EIS No. 20220179, Final Supplement, USACE, LA, West Shore Lake Pontchartrain Hurricane and Storm Damage Risk Reduction Study, Review Period Ends: 01/03/2023, Contact: Landon D. Parr 504–862–1908.

Amended Notice

EIS No. 20220141, Draft, USCG, WA, Expansion and Modernization of Base Seattle, Comment Period Ends: 12/16/2022, Contact: Dean Amundson 510–637–5541.

Revision to FR Notice Published 10/07/2022; Extending the Comment Period from 12/02/2022 to 12/16/2022.

Dated: November 28, 2022.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–26278 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0217; FRL–10450–01–OAR]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) is announcing a public meeting of the Clean Air Act Advisory Committee (CAAAC) to be conducted via remote/virtual participation only. The EPA renewed the CAAAC charter on October 31, 2022, to provide independent advice and counsel to EPA on economic, environmental, technical, scientific and enforcement policy issues associated with implementation of the Clean Air Act of 1990.

DATES: The CAAAC will hold its next public meeting remotely/virtually on Wednesday, December 14, 2022, from 1:00 p.m. to 2:30 p.m. (EST). Members of the public may register to listen to the meeting or provide comments, by emailing *caaac@epa.gov* by 5:00 p.m. (EST) December 13, 2022.

FOR FURTHER INFORMATION CONTACT: Lorraine Reddick, Designated Federal Official, Clean Air Act Advisory Committee (6103A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–1293;

email address: *reddick.lorraine@epa.gov.* Additional information about this meeting, the CAAAC, and its subcommittees and workgroups can be found on the CAAAC website: *http://www.epa.gov/caaac/.*

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. App. 2 section 10(a)(2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next public meeting remotely/virtually on December 14, 2022, 1:00 p.m. to 2:30 p.m. (EST).

The committee agenda and any documents prepared for the meeting will be publicly available on the CAAAC website at *http://www.epa.gov/caaac/* prior to the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available on the CAAAC website or by contacting the Office of Air and Radiation Docket and requesting information under docket EPA–HQ–OAR–2022–0217. The docket office can be reached by email at: *a-and-r-Docket@epa.gov* or FAX: 202–566–9744.

For information on access or services for individuals with disabilities, please contact Lorraine Reddick at *reddick.lorraine@epa.gov,* preferably at least 7 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: November 29, 2022.

Lorraine Reddick,

Designated Federal Officer, Office of Air Policy and Program Support.

[FR Doc. 2022–26259 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0492; FRL–10432–01–OCSPP]

United States Department of Justice and Parties to Certain Litigation; Transfer of Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide related information submitted to the Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to the U.S. Department of Justice (DOJ) and parties to certain litigation. This transfer of data is in accordance with the CBI regulations governing the disclosure of potential CBI in litigation.

DATES: Access to this information by DOJ and the parties to certain litigation is ongoing and expected to continue during the litigation as discussed in this Notice.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2659; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION: This notice is being provided pursuant to 40 CFR 2.209(d) to inform affected businesses that EPA, via DOJ, will provide certain information to the parties and the Court in the matter of *Center for Biological Diversity et al.* v. *United States Environmental Protection Agency et al.,* Case No. 4:20-cv-00555–DCB (D. Ariz.) (''Dicamba Litigation''). The information is contained in documents that have been submitted to EPA pursuant to FIFRA and FFDCA by pesticide registrants or other data-submitters, including information that has been claimed to be, or determined to potentially contain, CBI. In the Dicamba Litigation, the plaintiffs seek judicial review of three EPA registration decisions and related registration amendments for products that contain dicamba for use on dicamba-tolerant cotton and soybeans, issued under FIFRA, 7 U.S.C. 136 *et seq.*

The documents are being produced as part of the Administrative Record of the decisions at issue and include documents that registrants or other data-submitters may have submitted to EPA regarding the pesticide dicamba, and that may be subject to various release restrictions under federal law. The information includes documents submitted with pesticide registration applications and may include CBI as well as scientific studies subject to the disclosure restrictions of FIFRA section 10(g), 7 U.S.C. 136h(g).

All documents that may be subject to release restrictions under federal law are designated as ''Protected Information'' under a Protective Order that was entered by the court in the Dicamba Litigation on November 10, 2022 (Doc. No. 93). The Protective Order precludes public disclosure of any such documents by the parties in this action who have received the information from EPA and limits the use of such documents to litigation purposes only. If filed with the Court, the Protective Order requires that such documents be filed under seal and not be available for public review.

Authority: 7 U.S.C. 136 *et seq.;* 21 U.S.C. 301 *et seq.*

Dated: November 22, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022–26251 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0624; FRL–10416–01–OCSPP]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions were granted during the period July 1, 2022, to September 30, 2022, to control unforeseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the emergency exemption.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0624, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. Background

EPA has granted emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific.

Under FIFRA section 18 (7 U.S.C. 136p), EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A ''specific exemption'' authorizes use of a pesticide against specific pests for a specific crop/site on a limited acreage, or other unit for treatment (*e.g.,* square footage, cartons of produce in a particular State. Most emergency exemptions are specific exemptions.

2. ''Quarantine'' and ''public health'' exemptions are emergency exemptions issued for quarantine or public health purposes. These are requested less frequently than specific exemptions.

3. A ''crisis exemption'' is initiated by a State or Federal agency (and is concurred upon by EPA) when there is insufficient time to request and obtain EPA permission for emergency use of a pesticide under one of the other types of emergency exemptions.

EPA may deny an emergency exemption request: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in ''a reasonable certainty of no harm'' to human health, including exposure of infants and children to residues of the pesticide.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the ''reasonable certainty of no harm standard'' of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption, the type of exemption, the pesticide authorized, the pests, the crop or use for which authorized, number of acres or other unit for treatment (if applicable), and the effective date of the exemption. EPA also gives the **Federal Register** citation for the time-limited tolerance, if any, and notes when a Notice of Receipt (if required under 40 CFR 166.24) was published in the **Federal Register**.

III. Emergency Exemptions

A. U.S. States and Territories

Arkansas

Department of Agriculture

Specific exemption: EPA authorized the use of thiamethoxam on a maximum of 450,000 acres of rice to control rice stink bug. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.565(b). The authorization was effective July 27, 2022.

Florida

Department of Agriculture and Consumer Services

Specific exemption: EPA authorized the use of clothianidin on a maximum of 125,376 acres of immature (3 to 5 years old) citrus trees to manage the transmission of Huanglongbing (HLB) disease vectored by the Asian citrus psyllid. A time-limited tolerance in connection with this action supports this emergency use and is established in 40 CFR 180.586(b). The authorization was effective September 28, 2022.

Louisiana

Department of Agriculture and Forestry

Quarantine exemption: EPA authorized the use of fipronil to control an invasive crazy ant species (commonly referred to as the Tawny Crazy Ant) around the outside of manmade structures, in parishes where the ant has been confirmed. The authorization was effective September 27, 2022.

Michigan

Department of Agriculture and Rural Development

Quarantine exemption: EPA authorized the use of pyrethrins and piperonyl butoxide to eradicate Red Swamp Crayfish on a maximum 6.98 acres across sixteen ponds in Southeast Michigan. This is a non-food/non-feed use and the authorization was effective August 24, 2022.

Mississippi

Department of Agriculture and Commerce

Specific exemption: EPA authorized the use of thiamethoxam on a maximum of 50,000 acres of rice to control rice stink bug. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.565(b). The authorization was effective July 28, 2022.

Quarantine exemption: EPA authorized the use of fipronil to control an invasive crazy ant species (commonly referred to as the Tawny Crazy Ant) around the outside of manmade structures, in parishes where the ant has been confirmed. The authorization was effective September 27, 2022.

Missouri

Department of Agriculture

Specific exemption: EPA authorized the use of thiamethoxam on a maximum of 45,000 acres of rice to control rice stink bug. Time-limited tolerances in connection with a previous action support this emergency use and are established in 40 CFR 180.565(b). The authorization was effective August 12, 2022.

Texas

Department of Agriculture

Quarantine exemption: EPA authorized the use of fipronil to control an invasive crazy ant species (commonly referred to as the Tawny Crazy Ant) around the outside of manmade structures, in parishes where the ant has been confirmed. The authorization was effective September 27, 2022.

B. Federal Departments and Agencies

United States Department of Agriculture

Animal and Plant Health Inspection Service

Quarantine Exemption: EPA authorized the use of acetic acid (vinegar) on hard nonporous surfaces to control African swine fever virus. The authorization was effective September 9, 2022.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 28, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022–26249 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2022–0833; FRL–10463–01–ORD]

Availability of the IRIS Assessment Plan and Protocol for Assessing Cancer Risk From Inhalation Exposure to Cobalt and Cobalt Compounds; Public Science Meeting Postponement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting postponement.

SUMMARY: The Environmental Protection Agency (EPA) is postponing the public science meeting to discuss the ''IRIS Assessment Plan and Protocol for Assessing Cancer Risk from Inhalation Exposure to Cobalt and Cobalt Compounds.'' The public science webinar originally scheduled for November 30, 2022 will be postponed and a new meeting date will be scheduled in early 2023. EPA will announce the public meeting date and registration details on the EPA IRIS website (*https://www.epa.gov/iris*) and via EPA's IRIS listserv. To register for the IRIS listserv, visit IRIS website at *https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect.*

DATES: The public meeting announced in the **Federal Register** published at 87 FR 68151 on November 14, 2022 is being postponed. A new meeting date will be scheduled in early 2023. The public comment period on the document remains unchanged.

ADDRESSES: EPA will announce the public meeting date and registration details on the EPA IRIS website (*https://www.epa.gov/iris*) and via EPA's IRIS listserv.

FOR FURTHER INFORMATION CONTACT: For technical information on the draft IRIS Assessment Plan and Protocol for Assessing Cancer Risk From Inhalation Exposure to Cobalt and Cobalt Compounds, contact Mr. Dahnish Shams, CPHEA; *telephone:* 202–564–2758; or *email: shams.dahnish@epa.gov.*

Wayne Cascio,

Director, Center for Public Health and Environmental Assessment.

[FR Doc. 2022–26238 Filed 12–1–22; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Board of Directors Meeting

SUMMARY: Notice of the forthcoming regular meeting of the Board of Directors of the Farm Credit System Insurance Corporation (FCSIC), is hereby given in accordance with the provisions of the Bylaws of the FCSIC.

DATES: 10 a.m., Wednesday, December 7, 2022.

ADDRESSES: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to observe, at least 24 hours in advance, visit *FCSIC.gov*, select ''News & Events,'' then select ''Board Meetings.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

FOR FURTHER INFORMATION CONTACT: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public. The following matters will be considered:

Portions Open to the Public

- Approval of October 12, 2022, Minutes
- Quarterly FCSIC Financial Reports
- Quarterly Report on Insured Obligations
- Quarterly Report on Annual Performance Plan

Portions Closed to the Public

- Report on Insurance Risk
- Federal Managers Financial Integrity Act Review
- Auditor Selection Process
- Audit Plan for the Year Ended December 31, 2022
- Executive Session of the Audit Committee with Auditor

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2022–26210 Filed 12–1–22; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 116176]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (''Privacy Act''), this document announces a new computer matching program the Federal Communications Commission (''FCC'' or ''Commission'' or ''Agency'') and the Universal Service Administrative Company (USAC) will conduct with the Arizona Department of Economic Security. The purpose of this matching program is to verify the eligibility of applicants to and subscribers of Lifeline, and the Affordable Connectivity Program (ACP), both of which are administered by USAC under the direction of the FCC. More information about these programs is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before January 3, 2023. This computer matching program will commence on January 3, 2023, and will conclude 18 months after the effective date.

ADDRESSES: Send comments to Elliot S. Tarloff, FCC, 45 L Street NE, Washington, DC 20554, or to *Privacy@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Elliot S. Tarloff at 202–418–0886 or *Privacy@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Lifeline program provides support for discounted broadband and voice services to low-income consumers. Lifeline is administered by the Universal Service Administrative Company (USAC) under FCC direction. Consumers qualify for Lifeline through proof of income or participation in a qualifying program, such as Medicaid, the Supplemental Nutritional Assistance Program (SNAP), Federal Public Housing Assistance, Supplemental Security Income (SSI), Veterans and Survivors Pension Benefit, or various Tribal-specific federal assistance programs.

In the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182, 2129–36 (2020), Congress created the Emergency Broadband Benefit Program, and directed use of the National Verifier to determine eligibility based on various criteria, including the qualifications for Lifeline (Medicaid, SNAP, etc.). EBBP provided $3.2 billion

in monthly consumer discounts for broadband service and one-time provider reimbursement for a connected device (laptop, desktop computer or tablet). In the Infrastructure Investment and Jobs Act, Pub. L. 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52), Congress modified and extended EBBP, provided an additional $14.2 billion, and renamed it the Affordable Connectivity Program (ACP). A household may qualify for the ACP benefit under various criteria, including an individual qualifying for the FCC's Lifeline program.

In a Report and Order adopted on March 31, 2016, (81 FR 33026, May 24, 2016) (*2016 Lifeline Modernization Order*), the Commission ordered USAC to create a National Lifeline Eligibility Verifier (''National Verifier''), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for ACP. The purpose of this matching program is to verify the eligibility of Lifeline and ACP applicants and subscribers by determining whether they receive SNAP and Tribal Temporary Assistance for Needy Families (Tribal TANF) benefits administered by the Arizona Department of Economic Security.

Participating Agencies: Arizona Department of Economic Security.

Authority for Conducting The Matching Program: The authority for the FCC's ACP is Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52); 47 CFR part 54. The authority for the FCC's Lifeline program is 47 U.S.C. 254; 47 CFR 54.400 through 54.423; Lifeline and Link Up Reform and Modernization, *et al.,* Third Report and Order, Further Report and Order, and Order on Reconsideration, 31 FCC Rcd 3962, 4006–21, paras. 126–66 (2016) (*2016 Lifeline Modernization Order*).

Purpose(s): The purpose of this modified matching agreement is to verify the eligibility of applicants and subscribers to Lifeline, as well as to ACP and other Federal programs that use qualification for Lifeline as an eligibility criterion. This new agreement will permit eligibility verification for the Lifeline program and ACP by checking an applicant's/subscriber's participation in SNAP and Tribal TANF in Arizona. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for ACP benefits.

Categories of Individuals: The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline and/or ACP benefits; are currently receiving Lifeline and/or ACP benefits; are individuals who enable another individual in their household to qualify for Lifeline and/or ACP benefits; are minors whose status qualifies a parent or guardian for Lifeline and/or ACP benefits; or are individuals who have received Lifeline and/or ACP benefits.

Categories of Records: The categories of records involved in the matching program include, but are not limited to, the last four digits of the applicant's Social Security Number, date of birth, and first and last name. The National Verifier will transfer these data elements to the Arizona Department of Economic Security, which will respond either ''yes'' or ''no'' that the individual is enrolled in a qualifying assistance program: SNAP and Tribal TANF administered by the Arizona Department of Economic Security.

Systems(s) of Records:

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB–1, Lifeline, which was published in the **Federal Register** at 86 FR 11526 (Feb. 25, 2021). The records shared as part of this matching program reside in the ACP system of records, FCC/WCB–3, Affordable Connectivity Program, which was published in the **Federal Register** at 86 FR 71494 (Dec. 16, 2021).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–26292 Filed 12–1–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1252; FR ID 116158]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

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.

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.

DATES: Written PRA comments should be submitted on or before January 31, 2023. 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: *OMB Control Number:* 3060–1252.

Title: Application to Participate in Rural Digital Opportunity Fund Auction, FCC Form 183.

Form Number: FCC Form 183.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions, and State, Local or Tribal governments.

Number of Respondents and Responses: 500 respondents and 500 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154, 214, 254 and 303(r) of the Communications Act of 1934, as amended.

Total Annual Burden: 3,500 hours.

Total Annual Costs: No cost.

Nature and Extent of Confidentiality: Although most information collected in FCC Form 183 will be made available for public inspection, the Commission will withhold certain information collected in FCC Form 183 from routine public inspection. Specifically, the Commission will treat certain technical and financial information submitted in FCC Form 183 as confidential and as though the applicant has requested that this information be treated as confidential trade secrets and/or commercial information. In addition, an applicant may use the abbreviated process under 47 CFR 0.459(a)(4) to request confidential treatment of certain financial information contained in its FCC Form 183 application. However, if a request for public inspection for this technical or financial information is made under 47 CFR 0.461, and the applicant has any objections to disclosure, the applicant will be notified and will be required to justify continued confidential treatment of its request. To the extent that a respondent seeks to have other information collected in FCC Form 183 withheld from public inspection, the respondent may request confidential treatment pursuant to 47 CFR 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Commission will use the information collected to determine whether applicants are eligible to participate in the Rural Digital Opportunity Fund. On January 30, 2020 the Commission adopted the *Rural Digital Opportunity Fund Order,* WC Docket Nos. 19–126, 10–90, FCC 20–5 set a budget of up to $20.4 billion to support broadband networks in rural America.

To implement the Rural Digital Opportunity Fund auction, the Commission adopted rules for the Rural Digital Opportunity Fund auction, including the adoption of a two-stage application process. Any entity that wished to participate in the Rural Digital Opportunity Fund auction was required to submit the FCC Form 183 short-form application to demonstrate its qualifications to bid. Accordingly, the Commission collects this information pursuant to section 54.804(a) of the Commission's rules 47 CFR 54.804(a). Based on the Commission's experience with auctions and consistent with the record, this two-stage collection of information balances the need to collect information essential to conduct a successful auction with administrative efficiency.

Under this information collection, the Commission will collect information that will be used to determine whether an applicant is legally qualified to participate in an auction for Rural Digital Opportunity Fund support. To aid in collecting this information, the Commission will use FCC Form 183, which the public will use to provide the necessary information and certifications. Commission staff will review the information collected on FCC Form 183 as part of the pre-auction process, prior to the start of the auction, and determine whether each applicant satisfies the Commission's requirements to participate in an auction for Rural Digital Opportunity Fund support. Without the information collected on FCC Form 183, the Commission will not be able to determine if an applicant is legally qualified to participate in the auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. Any additional revisions or new collections for OMB review that address other reforms adopted in the *Rural Digital Opportunity Fund Order* will be submitted at a later date.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–26299 Filed 12–1–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012340–001.

Agreement Name: Hapag-Lloyd/Zim ECSA Space Charter Agreement.

Parties: Hapag Lloyd AG; ZIM Integrated Shipping Services Ltd.

Filing Party: Wayne Rohde, Cozen O'Connor.

Synopsis: The amendment revises the amount of space being chartered under the agreement.

Proposed Effective Date: 1/7/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/2022.

Dated: November 28, 2022.

William Cody,

Secretary.

[FR Doc. 2022–26214 Filed 12–1–22; 8:45 am]

BILLING CODE 6730–02–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–XXXX; Docket No. 2022–0001; Sequence No. 12]

Submission for OMB Review; Generic Clearance for the Collection of the Mission-Support Customer Satisfaction Survey

AGENCY: Office of Shared Services and Performance Improvement, Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding a new request for an OMB clearance.

SUMMARY: GSA is coordinating the development of the following proposed Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of the Mission-Support Customer Satisfaction Survey'' for approval under the Paperwork Reduction Act. This notice announces that GSA intends to submit this new collection to the Office of Management and Budget (OMB) for approval and will solicit comments on specific aspects for the proposed information collection.

DATES: Submit comments on or before January 3, 2023.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments''; or by using the search function.

FOR FURTHER INFORMATION CONTACT: Trey Bradley, Program Director, Strategic Data Initiatives, Organization, at telephone 202–716–6410 or via email to *trey.bradley@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Mission-Support Customer Satisfaction Survey (CSS) is an annual survey led by the Office of Management and Budget (OMB) and managed by the General Services Administration (GSA). The CSS began in 2015 as part of the Obama Administration's President's Management Agenda (PMA).

The CSS asks Federal employees to rate how satisfied they are with mission-support functions and services, how important specific mission-support services are to achieving mission outcomes, and whether a function serves as an effective strategic partner. Employees are asked to rate their perception of satisfaction, importance, and strategic partnership for 24 service areas on a seven-point Likert Scale within the following four support functions (functions are in *bold*):

Contracting: Pre-Award Activities; Contract Administration; Purchase Card Management.

Finance: Budget Formulation; Budget Execution; Financial Management Information & Analysis; Bill Payments; Bill Collections; Financial Risk Management.

Human Capital: Recruiting & Hiring; Training & Development; Work/Life Support; Employee Relations; Labor Relations; Performance & Recognition Management; Workforce Planning & Succession; Time & Attendance Management; Benefits Management; Retirement Planning & Processing.

Information Technology: IT Support; IT Communications & Collaboration; IT Equipment; Operations & Maintenance (O&M); Development, Modernization & Enhancement (DM&E).

The CSS is an annual, non-mandatory survey typically sent in early spring to all federal civilian employees at the 24 CFO Act Agencies.

The survey is distributed through email and responses are collected through an online survey platform. Each email sent contains a unique link to take the survey. Email contacts are obtained through the Office of Personnel Management's (OPM) Enterprise Human Resources Integration-Statistical Data Mart (EHRI–SDM). The EHRI–SDM is an information system that supports statistical analyses of federal personnel management programs. Agencies submit data from their personnel systems to the EHRI–SDM.

Agencies may choose to supplement or edit the EHRI–SDM email list for the purposes of this survey.

Survey reminders are sent once per week to those who have not yet taken the survey starting 7 days after the initial launch date until the closing of the survey. The survey is typically open for 6 to 8 weeks.

Individual survey responses are tracked for completeness so that reminders are sent only to those who have not yet taken the survey.

This is a confidential survey. To prevent identification of individual respondents, average satisfaction scores are excluded where the number of responses is fewer than 10. Once the survey is closed, all personal identifiable information (PII) is stripped from the data to protect privacy.

Survey participants only answered questions related to functions or services they had interaction within the previous year.

The response rate from year to year is approximately 20%.

Survey participants are allowed to opt out or choose not to take the survey.

The CSS is 508 compliant.

The CSS data is used by the Federal Government for three primary reasons:

- To provide a significant measure for quality of service provided, so that agencies can evaluate functional performance on quality as well as cost.
- To allow agencies to compare their performance to other agencies at the agency and bureau level.
- To provide the center of government a valuable data set to analyze and provide actionable insights for mission-support performance improvement.

Here are other specifics around how we plan to share the data:

- The items and the results of the items will be made publicly available for Federal agencies to assess their scores to identify areas for improvement;
- The general public, including researchers and the media, will also have access to this information;
- The collections are voluntary;
- Access to completed surveys will be limited to GSA and contractors who are involved in collecting and/or preparing the information for further analysis at OMB and distribution to other agencies:
- Information is only shared for the for the whole population and for certain subgroups. Neither federal agencies nor the public will receive data by subgroups that could be used to identify a specific individual or a person's specific response to a survey question.

The Agency has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

B. Annual Reporting Burden

Respondents: 300,100.
Responses per Respondent: 1.
Total Annual Responses: 1.
Hours per Response: 0.093 (338 seconds).
Total Burden Hours: 28,176.06.

C. Public Comments

A 60-day notice published in the **Federal Register** at 87 FR 39095 on June 30, 2022. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. ''3090–XXXX Generic Clearance for the Collection of the Mission-Support Customer Satisfaction Survey'' in all correspondence.

Beth Anne Killoran,

Deputy Chief Information Officer.

[FR Doc. 2022–26286 Filed 12–1–22; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1166]

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 ''Poison Center Collaborations for Public Health Emergencies (PCCPHE)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 26, 2022 to obtain comments from the public and affected agencies. CDC received no substantive public 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

Poison Center Collaborations for Public Health Emergencies (PCCPHE)(OMB Control No. 0920–1166, Exp. 04/30/2023)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting a three-year Paperwork Reduction Act (PRA) Revision of the Generic Information Collection Request (Generic ICR) titled Poison Center Collaborations for Public Health Emergencies (PCCPHE) (OMB Control No. 0920–1166; Expiration Date 04/30/2023).

CDC's key partner is America's Poison Centers, formerly known as the American Association of Poison Control Centers (AAPCC). America's Poison Centers is a national network of 55 poison centers working to prevent and treat poison exposures. America's Poison Centers manages its existing surveillance system called the National Poison Data System (NPDS) and provides CDC access to monitor this system under a cooperative agreement and a data license agreement.

When a public health emergency of interest emerges in NPDS, the CDC and America's Poison Centers hold a meeting to mutually decide whether the incident needs further investigation. For a public health emergency to be selected for call-back, adverse health effects must have occurred, and a response is needed to prevent further morbidity and mortality. The event must meet the following criteria: (1) the event is a public health emergency causing adverse health effects; (2) timely data are urgently needed to inform rapid public health action to prevent or reduce injury, disease, or death; (3) the incident is characterized by a natural or man-made disaster, contaminated food or water, a new or existing consumer product, or an emerging public health threat; (4) the incident has resulted in calls to a poison center, and the poison center agrees to conduct the call-back data collection; (5) the incident is domestic; and (6) data collection will be completed in 60 days or less.

The purpose of this Generic ICR is to create a timely mechanism to allow poison centers, supported by CDC, to follow-up with callers during select public health emergencies on exposure and health. These PCCPHE Generic Information Collections (GenICs) will obtain information on sources of exposure, scenario of exposure, health seeking behaviors following exposure, and awareness of health communication messaging. These additional data can help CDC identify interventions to improve health messaging meant to reduce exposure; improve disaster and emergency response; and prevent future events for the specific area or incident of interest.

Trained poison center staff will conduct the call-back telephone survey or will facilitate the call-back web survey, after administering consent. Respondents will include individuals who call poison centers about exposures related to the select public health emergencies. These respondents include adults, 18 years and older; adolescents, 15 to less than 18 years; and parents or guardians on behalf of their children less than 15 years of age.

In 2019, a PCCPHE GenIC, titled ''Risk Factors for Harmful Algal Blooms (HABs),'' was conducted to identify sources of and risk factors for HAB exposures. New information gained about HAB exposures were used improve HAB incident response, communication, and outreach at the state and national level. During the past three-year approval period, no PCCPHE GenICs were conducted; however, two NPDS-related follow-up studies were implemented using the Secretary's Public Health Emergency PRA Waiver for COVID–19. During a non-pandemic situation, these two studies would have used this Generic ICR. These studies assessed unintentional exposures associated with cleaning products (*e.g.,* bleach, hand sanitizers) in home settings to determine knowledge, attitudes, and practices regarding cleaning behaviors and help guide public health messaging.

Based on CDC's past experience, the following revisions affecting public burden are proposed. CDC plans to increase the annual number of public health emergencies of interest from two to three per year. CDC will reduce the estimated time per response from 40 minutes to 10 minutes. CDC plans to add web surveys as a second secure mode of collection to the currently approved telephone surveys. CDC will also increase the annual number of respondents from 150 to 500 per call-back investigation.

Based on these revisions, the annual time burden requested is 250 hours, which is an increase of 50 hours over the 200 hours previously approved. 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 burden per response (in hours)
Adult Poison Center Callers	Call-back Questionnaire for Self	1,200	1	10/60
Adolescent Poison Center Callers	Call-back Questionnaire for Self	150	1	10/60
Parent or Guardian Poison Center Callers	Call-back Questionnaire for Proxy	150	1	10/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–26306 Filed 12–1–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22CB]

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 ''Assessment for the *Get Ahead of Sepsis (GAOS)* Consumer and Healthcare Professional Campaign'' 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 January 31, 2022, to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessment for the Get Ahead of Sepsis (GAOS) Consumer and Healthcare Professional Campaign—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Sepsis is a life threating emergency, and it is the body's overactive and toxic response to an infection. Each year 1.7 million adults in the United States develop sepsis, with 270,000 fatalities. Sepsis is the leading cause of death in hospitals and one out of three hospital fatalities are due to sepsis infection. Sepsis management in U.S. hospitals is the highest when compared to inpatient cost for all other medical conditions. Annual costs are estimated to be over $62 billion.

In media and public health campaigns, antimicrobial resistance and sepsis are rarely presented together which does not make their linkage apparent. It has been concluded that sepsis and antimicrobial stewardship should not be discussed in isolation. Surprisingly, 24% of adults in the U.S. have never heard of sepsis, so this presents a unique opportunity for future messaging campaigns.

The goals of the Get Ahead of Sepsis (GAOS) educational campaign are to prevent and reduce infections that lead to sepsis and to optimize healthcare quality and patient safety by raising awareness, knowledge, and motivating behavior change related to sepsis prevention, early recognition, and appropriate treatment among consumer and healthcare professional (HCP) audiences. A panel survey will be utilized to recruit participants. Surveys will be distributed to consumer audiences and HCPs both before and after the media campaign and partner outreach.

Consumer audiences include:

(1) Cancer patients and their caregivers,

(2) Patients who survived severe COVID–19 or sepsis and their caregivers,

(3) Parents of children 12 and younger,

(4) Adults who care for a family member age 65+, (5) Men aged 65+ with one or more chronic conditions, and (6) Healthy adults 65+

HCP audiences include:

(1) Emergency Medical Services personnel,

(2) Nurse Practitioners and Physician Assistants who work at urgent care clinics,

(3) Emergency Department triage nurses,

(4) General medical ward staff,

(5) Primary care physicians,

(6) Long-term care (LTC) nurses, and

(7) LTC medical technicians and sitters.

This program evaluation will assist CDC in determining if the GAOS media campaign, along with partner outreach, was successful in raising knowledge and awareness and motivating behavior change among consumer and HCP audiences in select markets. The information gathered from this evaluation will also be used to inform refinement and implementation of the campaign (materials and tactics).

CDC requests OMB approval for an estimated 1366 annual burden hours. There is 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)
Consumers	*GAOS* Consumer Pre-Campaign web survey	945	1	20/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Consumers	*GAOS* Consumer Post-Campaign web survey	945	1	20/60
HCPs	*GAOS* HCP Pre-Campaign web survey	1103	1	20/60
HCPs	*GAOS* HCP Post-Campaign web survey	1103	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–26305 Filed 12–1–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Human Trafficking Youth Prevention Education Demonstration Grant Program Process Evaluation (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), in collaboration with the Office on Trafficking in Persons (OTIP), is proposing a new data collection activity for the Human Trafficking Youth Prevention Education (HTYPE) Demonstration Grant Program Process Evaluation. The process evaluation will explore whether the program is being implemented as intended, describe the successes and barriers that have been encountered, and highlight the changes that may be needed to support program implementation.

DATES: *Comments due within 30 days of publication.* The Office of Management and Budget (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.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The goal of the HTYPE Demonstration Grant Program is to support local educational agencies (LEA) to partner with a nonprofit or Non-Governmental Organization to build the capacity of schools to provide skills-based human trafficking prevention education for educators, other staff, and students, and to establish a Human Trafficking School Safety Protocol (HTSSP) that addresses the safety, security, and well-being of staff and students. Eight HTYPE Demonstration Program project grants were awarded in September 2020, with a period of performance of 36 months.

The purpose of the proposed information collection is to investigate and document how HTYPE projects approach and accomplish the goals of the HTYPE Demonstration Grant Program, inform ACF's efforts to support human trafficking prevention education in schools, and inform future evaluation efforts.

The proposed information collection activities include:

(1) One-time, semi-structured interviews or focus groups with trained LEA staff and implementers at select schools from each grant recipient site. Interviews/focus groups will include questions focused on implementation models, participant and implementer engagement, and implementation facilitators and barriers.

(2) One-time, semi-structured interviews with school staff related to the process and implementation of the HTSSP at select schools from each grant recipient site.

(3) One-time web survey with school administrators, which will include questions focused on school context and engagement, training mandates, implementation models, and implementation facilitators and barriers.

(4) One-time web survey with school staff tasked with implementing the HTYPE curriculum, which will include questions focused on educator training, student curriculum implementation models and quality, participant and implementer engagement, and implementation facilitators and barriers.

Respondents: LEA staff who have been involved in the HTYPE demonstration programs, including school leadership/administrators, curriculum implementers, and staff who have received human trafficking training.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
HTYPE Training Implementation Interview/Focus Group Guide	192	1	1.5	288
HTYPE HTSSP Walk-Through Guide	24	1	.75	18

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
HTYPE School Administrator Survey	321	1	.25	80
HTYPE Implementer Survey	1,437	1	.25	359

Estimated Total Annual Burden Hours: 745.

Authority: Section 105(d)(2) of the Trafficking Victims Protection Act (TVPA) of 2000 (Pub. L. 106–386) 105 [22 U.S.C. 7103].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–26224 Filed 12–1–22; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Administration for Children and Families Congressionally Directed Community Projects—Universal Project Description

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) is requesting approval of the ACF Congressionally Directed Community Projects—Universal Project Description (CDCP–UPD). This new information collection is proposed to collect information from recipients of ACF Congressionally Directed funds. A Congressional Directive is an authorization act or appropriations act that requires ACF to make an award(s) to a named recipient(s) for a particular program, project, activity, or geographic area(s).

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: CDCP recipients are identified annually by Congress through Appropriations for ACF. The CDCP–UPD will provide standard language and sections available for use by ACF program offices to solicit the required project description and project budget information from recipients of CDCP projects. Applications are required for CDCP as prescribed by HHS regulations 45 CFR 75.203. In addition to the information required by regulation, the CDCP–UPD will provide a selection of text options for the program offices to communicate the application requirements to the recipients, as required by 45 CFR 75.203.

The CDCP–UPD gathers information regarding the CDCP recipients' identified outcomes, project activities, timeline, organizational capacity, and budget and budget justification. The CDCP–UPD ensures sufficient information is obtained to assess risk, identify needs for technical assistance and monitoring, and address other requirements of Congress, ACF, the Department of Health and Human Services, the Office of Management and Budget, and funding and statutory regulation.

Respondents: The CDCP recipients are identified annually for funding under a Congressional Directive. In Fiscal Year 2022, there were 39 CDCP recipients identified for ACF funding. It is estimated that 200 CDCP recipients will be identified annually in future ACF appropriations.

ANNUAL BURDEN ESTIMATES

Information instrument	Annual Number of respondents (total over request period)	Annual Number of responses per respondent (total over request period)	Average burden per response (in hours)	Average annual burden (in hours)
Congressionally Directed Community Project—Uniform Project Description (CDCP–UPD)	200	1	30	6,000

Estimated Total Annual Burden Hours: 6000.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Social Security Act section 1110 [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–26304 Filed 12–1–22; 8:45 am]

BILLING CODE 4184–78–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number(s): 93.645]

Allotment Percentages to States for Child Welfare Services State Grants

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of biennial publication of allotment percentages for states under the Stephanie Tubbs Jones Child Welfare Services Program, Title IV–B, subpart 1 of the Social Security Act.

SUMMARY: As required by the Social Security Act, the Department is publishing the allotment percentage for each state under the Title IV–B Subpart 1, Stephanie Tubbs Jones Child Welfare Services Grant Program. Under the Act, the allotment percentages are one of the factors used in the computation of the federal grants awarded under the Program.

DATES: The allotment percentages will be effective for Federal Fiscal Years 2024 and 2025.

FOR FURTHER INFORMATION CONTACT: Sona Cook, Grants Management Officer, Family Protection & Resilience Portfolio, Office of Grants Management, Office of Administration, Administration for Children and Families, 330 C St. SW, Washington, DC 20201. Telephone (214) 767–2973, Email: *sona.cook@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The allotment percentage for each state is determined on the basis of paragraphs (b) and (c) of section 423 of the Social Security Act (42 U.S.C. 623(c)). These figures are available on the ACF internet homepage at *http://www.acf.hhs.gov/programs/cb/.* The allotment percentage for each state is as follows:

ALLOTMENT **

State	Percentage
Alabama	61.36%
Alaska *	47.30
Arizona	56.72
Arkansas	60.56
California	41.11
Colorado	45.00
Connecticut	34.14
Delaware	52.69
District of Columbia	24.82
Florida	51.68
Georgia	56.47
Hawaii *	52.02
Idaho	58.98
Illinois	47.87
Indiana	56.30
Iowa	55.36
Kansas	53.44
Kentucky	60.40
Louisiana	57.62
Maine	54.45
Maryland	45.10
Massachusetts	34.71
Michigan	55.87
Minnesota	48.08
Mississippi	64.46
Missouri	56.58
Montana	55.22
Nebraska	52.04
Nevada	53.31
New Hampshire	42.69
New Jersey	39.79
New Mexico	60.98
New York	40.11
North Carolina	56.48
North Dakota	49.35
Ohio	55.47
Oklahoma	57.53
Oregon	52.45
Pennsylvania	49.51
Rhode Island	50.00
South Carolina	58.85
South Dakota	49.99
Tennessee	56.08
Texas	52.95
Utah	56.48
Vermont	50.98
Virginia	47.94
Washington	42.74
West Virginia	62.07
Wisconsin	53.25
Wyoming	44.61
Amer Samoa	70
Guam	70
Puerto Rico	70
N. Mariana	70
Virgin Islands	70

ALLOTMENT **—Continued

* State Percentage = 50% of year average divided by the National United States 3-year average.

** State Percentage minus 100% yields the IV-BI allotment percentage.

[1] Allotment Percentage has been adjusted in accordance with section 423(b)(1).

Statutory Authority: Section 423(c) of the Social Security Act (42 U.S.C. 623(c)).

Elizabeth Leo,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2022–26272 Filed 11–29–22; 4:15 pm]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: National Institutes of Health and Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services delegates to the National Institutes of Health (NIH) Director and the Food and Drug Administration (FDA) Commissioner the authorities vested in the Secretary of Health and Human Services under Section 3 of the Accelerating Access to Critical Therapies for ALS Act, as amended, to establish and implement a Public-Private Partnership for rare neurodegenerative diseases. These authorities may be redelegated. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to submit reports to Congress and promulgate regulations.

DATES: This authority delegation was approved by the Secretary of Health and Human Services on November, 29, 2022.

Dated: November 29, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–26280 Filed 12–1–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, December 5, 2022, 12:00 p.m. to December 7, 2022, 5:00 p.m., National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 which was published in the **Federal Register** on November 22, 2022, FR Doc 2022–25392, 87 FR 71344. This notice is being amended to change the closed session time from 11:00 a.m.–1:05 p.m. to 12:00 p.m.–1:00 p.m. on December 5, 2022.

The meeting is partially closed to the public.

Dated: November 28, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–26216 Filed 12–1–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket Number: USCG–2022–0808]

Area Maritime Security Advisory Committee for New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Solicitation for membership.

SUMMARY: This notice requests individuals interested in serving on the New Orleans Area Maritime Security Advisory Committee (AMSC) submit their applications for membership to the Captain of the Port (COTP) Sector New Orleans.

DATES: Requests for membership should reach the U.S. Coast Guard COTP Sector New Orleans by 02 January 2022.

ADDRESSES: Applications for membership should be submitted to the COTP at the following address: Commander, Sector New Orleans, Attn: Mr. Roy Ford, New Orleans AMSC Executive Secretary, 200 Hendee St., New Orleans, LA 70114–1402.

FOR FURTHER INFORMATION CONTACT: For questions, regarding application submission or AMSC in general please contact Mr. Roy Ford, New Orleans AMSC Executive Secretary; phone: (504) 365–2116.

SUPPLEMENTARY INFORMATION:

Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code, and authorized the Secretary of the Department in which the Coast Guard is operating to establish Area Maritime Security Advisory Committees for any port area of the United States. (See 46 U.S.C. 70116; 46 U.S.C. 70112; 33 CFR 1.05–1, 6.01; Department of Homeland Security Delegation No. 0170.1). The MTSA includes a provision exempting these AMSCs from the Federal Advisory Committee Act (FACA), Public Law 92–436, and 86 Stat. 470 (5 U.S.C. App. 2).

New Orleans AMSC Mission

The New Orleans AMSC shall assist the Captain of the Port in the development, review, update, and exercising of the Area Maritime Security Plan (AMSP) for their respective area of responsibility. Such matters may include, but are not limited to: identifying critical port infrastructure and operations; identifying risks (threats, vulnerabilities, and consequences); determining mitigation strategies and implementation methods; developing strategies to facilitate the recovery of the Maritime Transportation System after a Transportation Security Incident; developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; providing advice to, and assisting the Captain of the Port in developing and maintaining the AMSP. Details regarding the specific objectives of the New Orleans AMSC can be found in the charter.

AMSC Composition

The composition of an AMSC, to include the New Orleans AMSC, is prescribed under 33 CFR 103.305. Pursuant to that regulation, members may be selected from the Federal, Territorial, or Tribal government; State government and political subdivisions of the State; local public safety, crisis management, and emergency response agencies; law enforcement and security organizations; maritime industry, including labor; other port stakeholders having a special competence in maritime security; and port stakeholders affected by security practices and policies.

AMSC Membership

Members of the AMSC should have at least five years of experience related to maritime or port security operations. The New Orleans AMSC has 16 members. We are seeking to fill 10 vacancies with this solicitation. Members' terms of office will be for five years; however, a member is eligible to serve additional terms of office based on COTP discretion. Members will not receive any salary or other compensation for their service on an AMSC.

Request for Applications

Please submit an application or nomination to the address indicated under the **ADDRESSES** section of this notice. Those seeking membership are not required to submit formal applications to the local Captain of the Port; however, we encourage the submission of resumes highlighting experience in the maritime and security industries.

Dated: November 23, 2022.

Kelly K. Denning,

Captain, U.S. Coast Guard, Captain of the Port/Federal Maritime Security Coordinator New Orleans.

[FR Doc. 2022–26225 Filed 12–1–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0579]

National Merchant Marine Personnel Advisory Committee; Vacancy

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard is accepting applications to fill one vacancy on the National Merchant Marine Personnel Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to personnel in the United States merchant marine, including the training, qualifications, certification, documentation, and fitness of mariners.

DATES: Completed applications must reach the U.S. Coast Guard on or before January 3, 2023.

ADDRESSES: Applications must be emailed to Mrs. Megan Johns Henry at *megan.c.johns@uscg.mil,* with the subject line ''Application for NMERPAC.''

FOR FURTHER INFORMATION CONTACT: Mrs. Megan Johns Henry, Alternate Designated Federal Officer of the National Merchant Marine Personnel Advisory Committee; telephone 202–372–1255 or email at *megan.c.johns@uscg.mil.*

SUPPLEMENTARY INFORMATION: The National Merchant Marine Personnel Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law 115–282, 132 Stat. 4192, (codified in 46 U.S.C. 15105). The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. Appendix), and 46 U.S.C. 15109. The Committee provides advice, consults with, and make recommendations to the Secretary of Homeland Security, via the

Commandant of the U.S. Coast Guard, on matters relating to personnel in the United States merchant marine, including the training, qualifications, certification, documentation, and fitness of mariners.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year. The meetings are held at a location selected by the U.S. Coast Guard.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel Regulations.

Under provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. Members serve at the pleasure of the Secretary of Homeland Security and maybe be removed prior to the end of their term for just cause. The Secretary of Homeland Security may require an individual to have passed an appropriate security background examination before appointment to the Committee, 46 U.S.C. 15109(f)(4). Committee members are required to attend and participate in meetings regularly. Members may be recommended for removal if they miss two consecutive meetings without a valid reason that is acceptable to the Chair of the Committee and the Designated Federal Officer.

In this solicitation for Committee members, we will consider applications for the position of engineering officer who represents merchant marine engineering officers. Applicants must be United States citizens holding active licenses or certificates issued under 46 U.S.C. chapter 71, as an engineering officer licensed as a chief engineer any horsepower (applicants must currently hold a Merchant Mariner Credential endorsed as Chief Engineer of unlimited horsepower).

Each member of the Committee serves as a representative and must have particular expertise, knowledge, and experience on matters related to personnel in the United States merchant marine, including the training, qualifications, certification, documentation, and fitness of mariners.

In order for the Department of Homeland Security (DHS), to fully leverage broad-ranging experience and education, the Committee must be diverse with regard to professional and technical expertise. DHS is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your application to *megan.c.johns@uscg.mil* provided in the **ADDRESSES** section of this notice. Applications must include: (1) a cover letter expressing interest in an appointment to the National Merchant Marine Personnel Advisory Committee; (2) a resume detailing the applicant's relevant experience; and (3) a brief biography of the applicant.

The U.S. Coast Guard will not consider incomplete or late applications.

Dated: November 28, 2022.

Benjamin J. Hawkins,

Deputy Director, Commercial Regulations and Standards.

[FR Doc. 2022–26223 Filed 12–1–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–1066]

Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Infrastructure Investment and Jobs Act; Fiscal Year 2022

SUMMARY: The Coast Guard is publishing this notice to satisfy a requirement of the Infrastructure Investment and Jobs Act that requires a detailed accounting of the projects, programs, and activities funded under the national recreational boating safety program provision of the Act be published annually in the **Federal Register**. This notice specifies the funding amounts the Coast Guard has committed, obligated, or expended during fiscal year 2022, as of September 30, 2022.

FOR FURTHER INFORMATION CONTACT: For questions on this notice please contact Mr. Jeff Decker, U.S. Coast Guard, Regulations Development Manager, (202) 372–1507 or mail to: *RBSInfo@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

Since 1998, Congress has passed a series of laws providing funding for projects, programs, and activities funded under the national recreational boating safety program, which is administered by the U.S. Coast Guard. For a detailed description of the legislative history, please see the Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Fixing America's Surface Transportation Act; Fiscal Year 2021 Notice published in the **Federal Register** on November 16, 2021 (86 FR 63407).

These funds are available to the Secretary from the Sport Fish Restoration and Boating Trust Fund (Trust Fund) established under 26 U.S.C. 9504(a) for payment of Coast Guard expenses for personnel and activities directly related to coordinating and carrying out the national recreational boating safety program. Amounts made available under this subsection remain available during the two succeeding fiscal years. Any amount that is unexpended or unobligated at the end of the three-year period during which it is available shall be withdrawn by the Secretary and allocated to the States in addition to any other amounts available for allocation in the fiscal year in which they are withdrawn or the following fiscal year.

Use of these funds requires compliance with standard Federal contracting rules with associated lead and processing times resulting in a lag time between available funds and spending. The total amount of funding transferred to the Coast Guard from the Trust Fund, and committed, obligated, and/or expended during fiscal year 2022 for each project is shown below.

Specific Accounting of Funds

The total amount of funding transferred to the Coast Guard from the Sport Fish Restoration and Boating Trust Fund and committed, obligated, and/or expended during fiscal year 2022 for each project is shown in the chart below.

Project	Description	Cost
46 U.S.C. 43 Compliance: Inspection Program/Boat Testing Program.	Provided for continuance of the national recreational boat compliance inspection program, which began in January 2001.	$633,900
46 U.S.C. 43 Compliance: Staff Salaries	Provided for personnel to oversee manufacturer compliance with 46 U.S.C. 43 requirements.	550,660

Project	Description	Cost
46 U.S.C. 43 Compliance: Staff Travel	Provided for travel by employees of the Boating Safety Division to oversee manufacturer compliance with 46 U.S.C. 43 requirements.	36,582
Administrative Overhead	Provide for supplies and Materials to support the RBS Program	229,761
Boating Accident Report Database (BARD) Web System.	Provided for maintaining the BARD Web System, which enables reporting authorities in the 50 States, five U.S. Territories, and the District of Columbia to submit their accident reports electronically over a secure Internet connection.	683,401
National Boating Safety Advisory Council	Provided for travel performed by NBSAC members, meeting room costs and administrative costs to support the NBSAC.	14,875
Contract Personnel Support	Provided contract personnel to conduct boating safety-related research and analysis.	752,460
Grant Management Training	Provided to facilitate staff training on new grant management requirements	91,379
Recreational Boating Safety Program Travel.	Provided for travel by employees of the Boating Safety Division to gather background and planning information for new recreational boating safety initiatives.	157,350
Reimbursable Salaries	Provided for 18 personnel directly related to coordinating and carrying out the national recreational boating safety program.	3,733,340

Of the $12.786 million made available to the Coast Guard in fiscal year 2022, $0 has been committed, obligated, or expended and an additional $6.884 of prior fiscal year funds have been committed, obligated, or expended, as of September 30, 2022. The remainder of the FY21 and FY22 funds made available to the Coast Guard (approximately $16.048 million) may be retained for the allowable period for the National Recreational Boating Survey, the expected reengineering of the Boating Accident and Reporting Database, and other projects, or it may be transferred into the pool of money available for allocation through the state grant program.

Authority

This notice is issued pursuant to 5 U.S.C. 552 and 46 U.S.C. 13107(c)(4).

Dated: November 28, 2022.

Amy M. Beach,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2022–26212 Filed 12–1–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Announcement of the National Customs Automation Program Test Concerning the Submission Through the Automated Commercial Environment of Certain Unique Entity Identifiers for the Global Business Identifier Evaluative Proof of Concept

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) will conduct a National Customs Automation Program test regarding the electronic transmission of certain unique entity identifiers through the Automated Commercial Environment (ACE). This test, which is referred to as the ''Global Business Identifier Evaluative Proof of Concept'' (GBI EPoC), is for participation by entry filers (*i.e.,* importers of record and licensed customs brokers) for merchandise imported into the United States. Test participants will voluntarily provide specific global business identifiers (GBIs) for the manufacturers, sellers, and shippers of merchandise covered by specified types of entries, which are limited for purposes of this test to certain commodities and countries of origin. Test participants may also, optionally, provide specific GBIs for exporters, distributors, and packagers associated with the covered entries. The test will permit CBP and certain Partner Government Agencies (PGAs) to access the underlying data associated with the GBIs (referred to as the ''GBI data''), to determine whether the submission of GBIs at the time of entry filing will enable the enhanced tracing of the supply chains of certain commodities. This notice invites importers of record and licensed customs brokers to participate in the test, provides a description of the test, sets forth the criteria for participation, and invites public comments on all aspects of the test.

DATES: The GBI EPoC will commence on December 19, 2022, and will continue until July 21, 2023, subject to any extension, modification, or early termination as announced in the **Federal Register**. CBP will begin to accept requests from importers of record and licensed customs brokers to participate in the test on December 2, 2022, and CBP will continue to accept such requests until the GBI EPoC concludes. Public comments on the test are invited and may be submitted to the address set forth below at any time during the test period.

ADDRESSES: Comments and questions concerning this notice, or any aspect of the test, may be submitted at any time before or during the test period via email to Trade Policy and Programs, Office of Trade, U.S. Customs and Border Protection, at *GBI@cbp.dhs.gov*, with the subject line reading ''Comments/Questions on GBI EPoC.''

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact Julie L. Stoeber, Branch Chief, 1USG, Interagency Collaboration Division, Trade Policy and Programs Division, Office of Trade, U.S. Customs and Border Protection, at (202) 945–7064 or via email at *GBI@cbp.dhs.gov*, with a subject line reading ''Global Business Identifier Test—GBI.'' For technical questions related to ACE or Automated Broker Interface (ABI) transmissions, importers of record and licensed customs brokers should contact their assigned ACE or ABI client representatives, respectively. Interested parties without an assigned client representative should direct their questions to Tonya Perez, Director, Client Services Division, Office of Trade, U.S. Customs and Border Protection, at (571) 421–7477 or via email at *clientrepoutreach@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The National Customs Automation Program

The National Customs Automation Program (NCAP) was established by subtitle B of title VI—Customs Modernization in the North American Free Trade Agreement Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was focused on informed trade compliance and the development

of ACE, the planned successor to the Automated Commercial System (ACS). ACE is an automated and electronic system for commercial trade processing, intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while facilitating compliance with U.S. laws and regulations and reducing costs for U.S. Customs and Border Protection (CBP) and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality, which update the system and add new functionality.

Sections 411 through 414 of the Tariff Act of 1930 (19 U.S.C. 1411–1414), as amended, define and list the existing and planned components of the NCAP (section 411), promulgate program goals (section 412), provide for the implementation and evaluation of the program (section 413), and provide for Remote Location Filing (section 414). Section 411(a)(1)(A) lists the electronic entry of merchandise, section 411(a)(1)(B) lists the electronic entry summary of required information, and section 411(a)(1)(D) lists the electronic transmission of manifest information, as existing NCAP components. Section 411(d)(2)(A) provides for the periodic review of data elements collected in order to update the standard set of data elements, as necessary.

B. Global Business Identifier Evaluative Proof of Concept (GBI EPoC)

ACE is the system through which the U.S. Government has implemented the ''Single Window,'' the primary system for processing trade-related import and export data required by the PGAs that work alongside CBP in regulating specific commodities. The transition away from paper-based procedures has resulted in faster, more streamlined processes for both the U.S. Government and industry. To continue this progress, CBP began working with the Border Interagency Executive Council (BIEC) and the Commercial Customs Operations Advisory Committee (COAC) starting in 2017, to discuss the continuing viability of the data element known as the manufacturer or shipper identification code (MID).

Currently, importers of record provide the MID at the time of filing of the entry summary. *See generally* 19 CFR part 142. The 13-digit MID is derived from the name and address of the manufacturer or shipper, as specified on the commercial invoice, by applying a code constructed pursuant to instructions specified by CBP. *See* Customs Directive No. 3550–055, dated November 24, 1986 (available online at *https://www.cbp.gov/sites/default/files/documents/3550-055_3.pdf*). Although use of the MID has served CBP and the international trade community well in the past, it has become apparent that the MID is not always a consistent or unique number. For example, the MID is based upon the manufacturer or shipper name, address, and country of origin, and this data can change over time and/or result in the same MID for multiple entities. Also, while the MID provides limited identifying information, other global unique identifiers capture a broader swath of pertinent information regarding the entities with which they are associated (*e.g.,* legal ownership of businesses, specific business and global locations, and supply chain roles and functions). Changes in international trade and technology for tracking the flow of commodities have presented an opportunity for CBP and PGAs to explore new processes and procedures for identifying the parties involved in the supply chains of imported goods.

CBP has thus engaged in regular outreach with stakeholders, including, but not limited to, importers of record, licensed customs brokers, trade associations, and PGAs, with a goal of obtaining meaningful feedback on their existing systems and operations in order to establish a mutually beneficial global entity identifier system. As a result of these discussions, CBP developed the Global Business Identifier Evaluative Proof of Concept (GBI EPoC), which is an interagency trade transformation project that aims to test and develop a single entity identifier solution for CBP and PGAs to achieve trade facilitation and trade security by obtaining deeper insight into the legal structure of ''who is who'' across the spectrum of trade entities, and to understand more clearly ownership, affiliation, and parent-subsidiary relationships.

For purposes of the GBI EPoC, ACE has been modified to permit test participants to provide the following entity identifiers (GBIs) associated with manufacturers, shippers, and sellers of merchandise covered by entries that meet the GBI EPoC criteria (commodity + country of origin): nine (9) digit Data Universal Numbering System (D–U–N–S®), thirteen (13) digit Global Location Number (GLN), and twenty (20) digit Legal Entity Identifier (LEI). These GBIs will be provided in addition to other required entry data (which may include the MID); any GBIs associated with the importer of record itself need not be provided as part of this test. The GBIs associated with the manufacturers, shippers and sellers will be provided with the CBP Form 3461 (Entry/Immediate Delivery) data transmission via the ABI in ACE for formal entries for consumption (''entry type 01'' in ACE) and informal entries (''entry type 11'' in ACE). CBP will then access the underlying data (GBI data) associated with the D–U–N–S®, GLN, and LEI, as set forth in the agreements that CBP has entered into with Dun & Bradstreet (D&B), GS1, and the Global Legal Entity Identifier Foundation (GLEIF), respectively, in order to connect a specific entry and merchandise to a more complete picture of those entities' ownership, structure, and affiliations, among other information. D&B, GS1, and GLEIF are collectively referred to as the identity management companies (IMCs).

Through the GBI EPoC, CBP aims to leverage existing entity identifiers—the D–U–N–S®, GLN, and LEI—to develop a systematic, accurate, and efficient method for the trade to report, and the U.S. Government to uniquely identify, legal business entities, their different business locations and addresses, and their various functions and supply chain roles. CBP will consider whether these three GBI, singly, or in concert, ensure that CBP and PGAs receive standardized trade data in a universally compatible trade language. Moreover, CBP will examine whether the GBIs submitted to CBP can be easily verified, thus reducing uncertainties that may be associated with the information related to shipments of imported merchandise. CBP will also consider whether the GBI EPoC may ultimately prove to be a more far-reaching, interagency initiative, one that keeps with the vision and actualized promise of the ''Single Window,'' by providing better visibility into the supply chain for CBP and PGAs, thereby further reducing paper processing, expediting cargo release, and enhancing the traceability of supply chains.

II. Authorization for the Test

The Customs Modernization Act authorizes the Commissioner of CBP to conduct limited test programs or procedures designed to evaluate planned components of the NCAP. The GBI EPoC is authorized pursuant to 19 CFR 101.9(b), which provides for the testing of NCAP programs or procedures. *See* T.D. 95–21, 60 FR 14211 (March 16, 1995).

III. Conditions for the Test

The test is voluntary, and importers of record and licensed customs brokers who wish to participate in the test must comply with all of the conditions set forth below. The full effect of access to additional entity-related data based on submission of the GBIs will be a key evaluation metric of the test.

Participation in the test will provide test participants with the opportunity to test and give feedback to CBP on the GBI EPoC design and scope. Participation may also enable test participants to establish and test their digital fingerprints, such as more accurately identifying certain parties involved in their supply chains. In addition, participation may allow the trade community to better manage and validate their data and streamline their import data collection processes. Lastly, test participation may allow for the wider application of entity identifiers that are currently providing broad sector coverage and enhanced data analysis.

A. Obtaining Global Business Identifier (GBI) Numbers

Importers of record and licensed customs brokers who are interested in participating in the test must arrange to obtain the required D–U–N–S®, GLN, and LEI entity identifiers (the GBIs) from the manufacturers, shippers, and sellers of merchandise that are intended to be covered by future entries that will meet the conditions of the test (commodity + country of origin). For purposes of providing the information required for the test, the parties are defined as follows for each covered entry:

- Manufacturer (or supplier)—The party that last manufactures, assembles, produces, or grows the goods or the party supplying the finished goods in the country from which the goods are leaving for the United States.
- Shipper—The party that enters into a contract for carriage with, and arranges for delivery of the goods to, a carrier or transport intermediary for transportation to the United States.
- Seller—The last known party by whom the goods are sold or agreed to be sold. If the goods are to be imported otherwise than in pursuance of a purchase, the owner of the goods must be provided.

Optionally, test participants may also arrange to obtain the GBIs for exporters, distributors, and packagers that will be associated with these future entries and provide them to CBP on qualifying entries covered by this test.

A party may obtain its own GBI by contacting Dun and Bradstreet (D&B) at *https://www.dnb.com/duns-number.html,* regarding the D–U–N–S®; GS1 at *https://www.gs1.org/standards/id-keys/gln,* regarding the GLN; and Global Legal Entity Identifier Foundation (GLEIF) at *https://www.lei-identifier.com/lei-registration/,* regarding the LEI.

Once the manufacturers, shippers, and sellers (and, optionally, the exporters, distributors, and packagers) have obtained their own GBIs (the D–U–N–S®, GLN, and LEI), these parties should provide the resulting GBIs to the relevant importer of record or licensed customs broker participating in the test. If these parties experience any difficulty with obtaining any of the GBIs, the importer of record or licensed customs broker seeking to participate in the test should reach out to CBP by email at *GBI@cbp.dhs.gov.* The test participant is not required to obtain or submit GBIs pertaining to their own entity.

Importers of record and licensed customs brokers are reminded that they are responsible for obtaining any necessary permissions with respect to providing to CBP the GBIs for manufacturers, shippers, and sellers (and, optionally, for exporters, distributors, and packagers) in the supply chains of the imported merchandise for which they file the specified types of entries subject to the conditions of the test (commodity + country of origin). Therefore, prior to submitting their request to participate in the test to CBP, as discussed below, importers of record and licensed customs brokers should consult with these parties to ensure that these parties are willing to grant any necessary permissions to share their GBIs (which will also result in CBP's access to the underlying GBI data associated with those GBIs, as described above) with CBP under the auspices of the test.

B. Submission of Request To Participate in the GBI EPoC

The test is open to all importers of record and licensed customs brokers provided that these parties have requested permission and are approved by CBP to participate in the test. Importers of record and licensed customs brokers seeking to participate in the test should email the GBI Inbox (*GBI@cbp.dhs.gov*) with the subject heading ''Request to Participate in the GBI EPoC.'' As part of their request to participate, importers of record and licensed customs brokers must agree to provide available GBIs with entry filings for merchandise that is subject to the conditions of the test and state that they intend to participate in the test. The request must include the potential participant's filer code and evidence that they have obtained all three GBIs (D–U–N–S®, GLN, and LEI), or are in the process of obtaining them, from the manufacturers, shippers, and sellers (and, optionally, exporters, distributors, and packagers) of merchandise that is subject to the conditions of the test (commodity + country of origin). They must also advise that they intend to import commodities that are subject to the test from the countries of origin that are subject to the test.

Test participants who are importers of record and do not self-file must advise CBP in their request that they have authorized their licensed customs broker(s) to file qualifying entries under the test on their behalf. Test participants who are licensed customs brokers must advise CBP that they have been authorized to file qualifying entries on behalf of importers of record whose shipments meet the test criteria (commodity + country of origin), as set forth below.

CBP will begin to accept requests to participate in the test on December 19, 2022 and will continue to accept them until the test concludes. Anyone providing incomplete information, or otherwise not meeting the test requirements, will be notified by email, and given the opportunity to resubmit their request to participate in the test.

C. Approval of GBI EPoC Participants

A party who wishes to participate in this test is eligible to do so as long as it is an importer of record or licensed customs broker who files type 01 (formal) or type 11 (informal) entries of merchandise that meet the conditions of the test (commodity + country of origin), and that party obtains the required GBIs from their supply chain partners. After receipt of a request to participate in the test, CBP will notify, by email, the importers of record and licensed customs brokers who are approved for participation and inform them of the starting date of their participation (noting that test participants may have different starting dates). Test participants must provide the GBIs they have received to CBP prior to the starting date of their participation (participants will also provide the GBIs to CBP again with each qualified entry filing meeting the requirements of the test). Test participants are considered to be bound by the terms and conditions of this notice and any subsequent modifications published in the **Federal Register**.

D. Criteria for Qualifying Entries

1. Commodities Subject to the GBI EPoC

The test will be limited to type 01 and type 11 entries of certain commodities, specifically alcohol, toys, seafood, personal items and medical devices. Accordingly, CBP has limited the test to entries of merchandise classifiable in specific subheadings of chapters 3, 16, 22, 30, 33, 63, 90, and 95 of the Harmonized Tariff Schedule of the United States (HTSUS), as set forth below.

Chapter 3: 0306.16.0003; 0306.16.0006; 0306.16.0009; 0306.16.0012; 0306.16.0015; 0306.16.0018; 0306.16.0021; 0306.16.0024; 0306.16.0027; 0306.16.0040; 0306.17.0004; 0306.17.0005; 0306.17.0007; 0306.17.0008; 0306.17.0010; 0306.17.0011; 0306.17.0013; 0306.17.0014; 0306.17.0016; 0306.17.0017; 0306.17.0019; 0306.17.0020; 0306.17.0022; 0306.17.0023; 0306.17.0025; 0306.17.0026; 0306.17.0028; 0306.17.0029; 0306.17.0041; 0306.17.0042; 0306.35.0020; 0306.35.0040; 0306.36.0020; 0306.36.0040; 0306.95.0020; and 0306.95.0040.

Chapter 16: 1605.21.0500; 1605.21.1020; 1605.21.1030; 1605.21.1050; 1605.29.0500; 1605.29.1010; and 1605.29.1040.

Chapter 22: 2203.00.0030; 2203.00.0060; 2203.00.0090; 2204.10.0030; 2204.10.0065; 2204.10.0075; 2204.21.5005; 2204.21.5015; 2204.21.5025; 2204.21.5025; 2204.21.5028; 2204.21.5035; 2204.21.5040; 2204.21.5050; 2204.21.5055; 2204.21.5060; 2204.21.8030; 2204.21.8060; 2208.30.3030; 2208.30.3060; 2208.40.4000; and 2208.60.2000.

Chapter 30: 3005.90.5010; 3005.90.5090.

Chapter 33: 3304.99.5000.

Chapter 63: 6307.90.6800.

Chapter 90: 9018.39.0020; 9018.39.0040; 9018.39.0050; and 9018.90.8000.

Chapter 95: 9503.00.0011; 9503.00.0013; 9503.00.0071; 9503.00.0073; and 9503.00.0090.

Test participants are encouraged to submit GBIs with all qualified entry filings that meet the conditions of the test so that CBP has a fulsome data set to evaluate; however, entries will not be rejected if GBIs are not submitted. Additional commodities may be added as CBP refines the scope of the test. CBP will announce the HTSUS subheadings for any additional commodities as a modification to the test in a subsequent **Federal Register** notice.

2. Countries of Origin Subject to the GBI EPoC

CBP has limited the test to entries of imported merchandise with the following countries of origin, which have been identified as representing both countries with a high risk of non-compliance with U.S. import laws and those that are partner countries, while covering a diversity of jurisdictions: (1) Australia; (2) Canada; (3) China; (4) France; (5) Italy; (6) Mexico; (7) New Zealand; (8) Singapore; (9) United Kingdom; and (10) Vietnam. Additional countries of origin may be added as CBP refines the scope of the test. CBP will announce any additional countries of origin as a modification to the test in a subsequent **Federal Register** notice.

E. Filing Entries With GBIs (via ABI in ACE)

Test participants must coordinate with their software vendors or technical teams to ensure that their electronic systems are capable of transmitting the D–U–N–S®, GLN, and LEI entity identifiers to CBP. During this test, CBP will only accept electronic submissions of GBIs via ABI in ACE with CBP Form 3461 (Entry/Immediate Delivery) filings for type 01 and type 11 entries. Upon selection to participate in the test, the test participants will be provided with technical information and guidance regarding the transmission of the GBIs to CBP with the CBP Form 3461 filings. The assigned ABI client representatives of the test participants will provide additional technical support, as needed.

F. CBP Access to Underlying GBI Data Associated With GBIs

As part of the test, CBP has entered into agreements with D&B, GS1, and GLEIF (the IMCs) for limited access to the underlying data (''GBI data'') that is associated with the GBIs for the duration of the test and for testing of CBP's automated systems.[1] The data elements for which CBP has entered into agreements with D&B, GS1, and GLEIF may include, but are not limited to: (1) entity identifier numbers, (2) official business titles; (3) names; (4) addresses; (5) financial data; (6) trade names; (7) payment history; (8) economic status; and (9) executive names. The data elements will be examined as part of the test.

Consistent with the agreements, CBP may access GBI data, combine it with CBP data, and evaluate the GBIs that the test participants provide with an entry filing. The GBI data will assist CBP and PGAs in determining the optimal combination of the three entity identifiers (the GBIs) that will provide the U.S. Government with sufficient entity data needed to support identification, monitoring, and enforcement procedures to better equip the U.S. Government to focus on high-risk shipments and bad actors.

CBP will process entries submitted pursuant to the test by analyzing the GBIs submitted via ABI in ACE and ensuring that the GBIs are submitted correctly. CBP will then evaluate the submitted entries to assess the ease and cost of obtaining each of the GBIs, evaluating each GBI to ensure that it is being submitted properly per the technical requirements that will be set forth in CBP and Trade Automated Interface Requirements (CATAIR), and ensuring that CBP is able to validate that each GBI is accurate using the underlying GBI data from the IMCs or otherwise known to CBP.

G. Partner Government Agencies (PGAs)

PGAs are important to the success of the test. Certain PGAs, which may receive GBIs and GBI data and are intended as core test beneficiaries, may use the GBIs and GBI data to improve risk management and import compliance. This may result in smarter, more efficient, and more effective compliance efforts. CBP will announce the PGAs who will receive GBIs and GBI data pursuant to the test in a notice to be published in the **Federal Register** at a later date.

H. Duration of Test

The test will commence on December 19, 2022, and will run until July 21, 2023, subject to any extensions, modifications or early termination as announced by way of a notice to be published in the **Federal Register**.

I. Misconduct Under the Test

Misconduct under the test may include, but is not limited to, submitting false GBIs with an entry filing. Currently, CBP does not plan to assess penalties against GBI EPoC participants that fail to timely and accurately submit GBIs during the test. CBP also does not anticipate shipment delays due to the failure to file or the erroneous filing of GBIs. However, test participants are expected to follow all other applicable

[1] As noted above, D&B, GS1, and GLEIF are IMCs. The GBI data consists of data provided by the relevant entity to the IMCs in order to generate a GBI—the D–U–N–S®, GLN, or LEI. GBIs allow CBP to link the underlying GBI data to specific entities and entries.

regulations and requirements associated with the entry process.

After an initial six-month period (or at such earlier time as CBP deems appropriate), a test participant may be subject to discontinuance from participation in this test for any of the following repeated actions:

- Failure to follow the terms and conditions of this test;
- Failure to exercise due diligence in the execution of participant obligations;
- Failure to abide by applicable laws and regulations that have not been waived; or
- Failure to deposit duties or fees in a timely manner.

If the Director, Interagency Collaboration Division (ICD), Trade Policy and Programs (TPP), Office of Trade (OT), finds that there is a basis to discontinue a participant's participation in the test, then CBP will provide written notice, via email, proposing the discontinuance with a description of the facts or conduct supporting the proposal. The test participant will be offered the opportunity to respond to the Director's proposal in writing within 10 business days of the date of the written notice. The response must be submitted to the ICD Director, TPP, OT, by emailing *GBI@cbp.dhs.gov,* with a subject line reading ''Appeal—GBI Discontinuance.''

The Director, ICD, will issue a final decision in writing on the proposed action within 30 business days after receiving a timely filed response from the test participant, unless such time is extended for good cause. If no timely response is received, the proposed notice becomes the final decision of CBP as of the date that the response period expires. A proposed discontinuance of a test participant's privileges will not take effect unless the response process under this paragraph has been concluded with a written decision that is adverse to the test participant, which will be provided via email.

J. Confidentiality

Data submitted and entered into ACE may include confidential commercial or financial information which may be protected under the Trade Secrets Act (18 U.S.C. 1905), the Freedom of Information Act (5 U.S.C. 552), and the Privacy Act (5 U.S.C. 552a). However, as stated in previous notices, participation in this or any of the previous ACE tests is not confidential and, therefore, upon receipt of a written Freedom of Information Act request, the name(s) of an approved participant(s) will be disclosed by CBP in accordance with 5 U.S.C. 552.

IV. Comments on the Test

All interested parties are invited to comment on any aspect of this test at any time. CBP requests comments and feedback on all aspects of this test, including the design, conduct and implementation of the test, in order to determine whether to modify, alter, expand, limit, continue, end, or fully implement this program. Comments should be submitted via email to *GBI@cbp.dhs.gov,* with the subject line reading ''Comments/Questions on GBI EPoC.''

V. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB).

The new GBI collection of information gathered under this test has been approved by OMB in accordance with the requirements of the PRA and assigned OMB control number 1651–0141. In addition, the Entry/Immediate Delivery Application and ACE Cargo Release (CBP Form 3461 and 3461 ALT) has been updated to accommodate the GBI test, and approved by OMB under OMB control number 1651–0024.

VI. Evaluation Criteria

The test is intended to evaluate the feasibility of replacing the current manufacturer or shipper identification code (MID) with unique entity identifiers (GBIs) to more accurately identify legal business entities, their different business locations and addresses, as well as their various functions and supply chain roles, based upon information derived from the unique D–U–N–S®, GLN, and LEI entity identifiers. The test will assist CBP in enforcing applicable laws and protecting the revenue, while fulfilling trade modernization efforts by assisting the agency in verifying the roles, functions and responsibilities that various entities play in a given participants' importation of merchandise. CBP's evaluation of the test, including the review of any comments submitted to CBP during the duration of the test, will be ongoing with a view to possible extension or expansion of the test.

CBP will evaluate whether the test: (1) improves foreign entity data for trade facilitation, risk management, and statistical integrity; (2) ensures U.S. Government access to foreign entity data; (3) institutionalizes a global, managed identification system; (4) implements a cost-effective solution; (5) obtains stakeholder buy-in; and (6) facilitates legal compliance across the U.S. Government. At the conclusion of the test, an evaluation will be conducted to assess the efficacy of the information received throughout the course of the test. The final results of the evaluation will be published in the **Federal Register** as required by section 101.9(b)(2) of the CBP regulations (19 CFR 101.9(b)(2)).

Should the GBI EPoC be successful and ultimately be codified under the CBP regulations, CBP anticipates that this data would greatly enhance ongoing trade entity identification and resolution, reduce risk, and improve compliance operations. CBP would also anticipate greater supply chain visibility and verified, validated information on legal entities, which will support better decision-making during customs clearance processes.

Dated: November 28, 2022.

AnnMarie R. Highsmith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2022–26213 Filed 12–1–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–0022–0046; OMB No. 1660–0143]

Agency Information Collection Activities: Proposed Collection; Comment Request; Federal Emergency Management Agency Individual Assistance Customer Satisfaction Surveys

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, with change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of

Individual Assistance customer satisfaction survey responses and information for assessment and improvement of the delivery of disaster assistance to individuals and households.

DATES: Comments must be submitted on or before January 31, 2023.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at *www.regulations.gov* under Docket ID FEMA–0022–0046. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jason Salazar, Program Analyst, Recovery Directorate, FEMA at *Jason.Salazar@FEMA.dhs.gov* or (940) 268–9245. You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This collection is in accordance with Executive Orders 12862, *Setting Customer Service Standards* (58 FR 48257, Sept. 11, 1993) and 13571, *Streamlining Service Delivery and Improving Customer Service* (76 FR 24339, May 2, 2011) requiring all Federal Agencies to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. The Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62, 107 Stat. 285) requires agencies to set missions and goals and measure performance against them and the GPRA Modernization Act of 2010 (Pub. L. 111–352, 31 U.S.C. 1116) requires quarterly performance assessments of government programs for the purposes of assessing agency performance and improvement. FEMA will fulfill these requirements by collecting customer satisfaction program information through surveys of the Recovery Directorate's external customers.

This is a request to reduce burden hours in order to comply with the Department of Homeland Security's Paperwork Reduction Act Burden Reduction Initiative. Burden has been reduced in the following ways:

1. Corrected inaccurate burden per response for electronic survey forms. Original estimates were prior to implementation of electronic surveys. Completion times are faster than original estimates.

2. A higher percentage of respondents prefer email surveys in recent years, which are faster to complete than phone surveys.

3. The burden hours allocated to qualitative research have been reduced based on recent utilization.

No changes have been made to the currently approved survey forms. This collection was previously approved in July 2021.

Collection of Information

Title: Federal Emergency Management Agency Individual Assistance Customer Satisfaction.

Type of Information Collection: Extension, with change, of a currently approved information collection.

OMB Number: 1660–0143.

FEMA Forms: FEMA Form FF–104–FY–21–159 (formerly 519–0–36), Initial Survey—Phone; FEMA Form FF–104–FY–21–160 (formerly 519–0–37), Initial Survey—Electronic; FEMA Form FF–104–FY–21–161 (formerly 519–0–38), Contact Survey—Phone; FEMA Form FF–104–FY–21–162 (formerly 519–0–39), Contact Survey—Electronic; FEMA Form FF–104–FY–21–163 (formerly 519–0–40), Assessment Survey—Phone; FEMA Form FF–104–FY–21–164 (formerly 519–0–41), Assessment Survey—Electronic; Focus Groups; One-on-One Interviews.

Abstract: Federal Agencies are required to survey their customers to determine the kind and quality of services customers want and their level of satisfaction with those services. Analysis from the survey is used to measure whether FEMA is meeting its mission of being accessible, timely, and effective when it comes to meeting the needs of disaster survivors.

Affected Public: Individuals or households.

Estimated Number of Respondents: 38,200.

Estimated Number of Responses: 38,200.

Estimated Total Annual Burden Hours: 5,893.

Estimated Total Annual Respondent Cost: $239,314.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $18,750.

Estimated Total Annual Cost to the Federal Government: $1,936,402.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2022–26281 Filed 12–1–22; 8:45 am]

BILLING CODE 9111–24–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2022–0168; FXIA16710900000–223–FF09A30000]

Marine Mammal Protection Act; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on species for which the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). With some exceptions, the MMPA prohibits activities with listed species unless Federal authorization is issued that allows such activities. This Act also requires that we invite public comment before issuing permits for any activity it otherwise prohibits with respect to any species.

DATES: We must receive comments by January 3, 2023.

ADDRESSES:

Obtaining Documents: The applications, application supporting

materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2022–0168.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2022–0168.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2022–0168; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, 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:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, this Act prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Service regulations regarding permits for any activity otherwise prohibited by the MMPA with respect to any foreign or native marine mammal species are available in title 50 of the Code of Federal Regulations in part 18.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

III. Permit Applications

We invite comments on the following applications.

Marine Mammal Protection Act

Applicant: North Slope Borough, Department of Wildlife Management, Anchorage, AK; Permit No. PER0046206

The applicant requests a reissuance of their permit to collect fecal samples, to collect tissue samples from dead individuals, and to conduct non-invasive sampling of wild walruses (*Odobenus rosmarus*) and polar bear (*Ursus maritimus*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: BBC Studios Ltd., Bristol, UK; Permit No. PER0031742

The applicant requests a permit to photograph (video and still photography) West Indian manatees (*Trichechus manatus*) in Florida, for the purpose of commercial photography. This notification covers activities to be conducted by the applicant over a 5-year period.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *https://www.regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

Timothy MacDonald,

Government Information Specialist, Branch of Permits, Division of Management Authority.

[FR Doc. 2022–26265 Filed 12–1–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[DOI–2022–0009; FF10T03000/234/FXGO16640970500]

Privacy Act of 1974; System of Records

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Rescindment of a system of records notice.

SUMMARY: The Department of the Interior (DOI) is issuing a public notice of its intent to rescind the U.S. Fish and Wildlife Service (FWS) Privacy Act system of records, INTERIOR/FWS–25, Contract and Procurement Records, from its existing inventory.

DATES: These changes take effect on December 2, 2022.

ADDRESSES: You may send comments identified by docket number [DOI–2022–0009] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: DOI_Privacy@ios.doi.gov.* Include docket number [DOI–2022–0009] in the subject line of the message.
- *U.S. mail or hand-delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2022–0009]. 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.*

You should be aware your entire comment including your personally identifiable information, such as your address, phone number, email address, or any other personal information in your comment, may be made publicly available at any time. While you may request to withhold your personally identifiable information from public review, we cannot guarantee we will be able to do so.

FOR FURTHER INFORMATION CONTACT: Jennifer L. Schmidt, Associate Privacy Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: IRTM, Falls Church, VA 22401, *FWS_Privacy@fws.gov* or (703) 358–2291.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, FWS is rescinding the INTERIOR/FWS–25, Contract and Procurement Records, system of records notice (SORN) and removing it from its system of records inventory. This system was used by FWS contracting officers and technical representatives to evaluate contract proposals submitted by members of the public. During a routine review, FWS determined that INTERIOR/FWS–25 SORN was superseded by INTERIOR/DOI–87, Acquisition of Goods and Services: FBMS, 73 FR 43766 (July 28, 2008), modification published at 86 FR 50156 (September 7, 2021), a Department-wide SORN for the Financial and Business Management System (FBMS), which supports DOI business and financial management functions for all bureaus and offices, including all procurement and contracting activity. Therefore, DOI is rescinding this FWS notice to avoid duplication of another SORN in accordance with the Office of Management and Budget Circular A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act.*

Rescinding the INTERIOR/FWS–25, Contract and Procurement Records, SORN will have no adverse impacts on individuals as the records are covered under the INTERIOR/DOI–87, Acquisition of Goods and Services: FBMS, SORN. This rescindment will also promote the overall streamlining and management of DOI Privacy Act systems of records.

SYSTEM NAME AND NUMBER:

INTERIOR/FWS–25, Contract and Procurement Records.

HISTORY:

48 FR 54721 (December 6, 1983); modification published at 73 FR 31877 (June 4, 2008).

Teri Barnett,

Departmental Privacy Officer, Department of the Interior.

[FR Doc. 2022–26311 Filed 12–1–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

[GX22EN05ESBJF00]

Advisory Council for Climate Adaptation Science Establishment; Request for Nominations

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior (DOI) is establishing and seeking nominations for the Advisory Council for Climate Adaptation Science (Council). The Council will advise the Secretary of the Interior on the establishment and operations of the U.S. Geological Survey (USGS) National Climate Adaptation Science Center (NCASC) and its nine regional Climate Adaptation Science Centers (CASCs).

DATES: Comments regarding the establishment of this Council must be submitted no later than December 19, 2022. Nominations for the Council must be submitted by January 16, 2023.

ADDRESSES: You may submit comments and/or nominations by any of the following methods:

- Mail nominations to Janet Cushing, U.S. Geological Survey, National Climate Adaptation Science Center, 12201 Sunrise Valley Drive Mailstop 516, Reston, VA 20192; or
- Email nominations to: *jcushing@usgs.gov*.

FOR FURTHER INFORMATION CONTACT: Janet Cushing, Council Designated Federal Officer, by U.S. mail at the U.S. Geological Survey, 12201 Sunrise Valley Drive Mailstop 516, Reston, VA 20192; by telephone at 703–648–4015; or by email at *jcushing@usgs.gov.*

SUPPLEMENTARY INFORMATION: The Council is established under the authority of the Secretary and regulated by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2). The Council's duties are strictly advisory and consist of, but are not limited to, providing recommendations on: (a) advising on the contents of a national strategy identifying key climate adaptation science priorities to advance the management of natural and cultural resources in the face of climate change; (b) advising on the nature, extent, and quality of relations with and engagement of key partners at the regional/CASC level; (c) advising on the nature and effectiveness of mechanisms to effectively deliver science information and tools, and build capacity, to aid the natural and cultural resource management community and decision-makers in adapting to a changing climate; (d) advising on mechanisms that may be employed by the NCASC to ensure high standards of scientific quality and integrity in its products, and to review and evaluate the performance of individuals CASCs, in advance of opportunities to re-establish expiring agreements; and (e) advising on the integration of equity, particularly for historically underserved communities, in the operation of the NCASC and regional CASCs.

The Council will meet approximately one to two times per year. The Secretary of the Interior will appoint members and their alternates to the Council to a 2- to 3-year term. The members of the Council shall comprise approximately 18 members who represent the diversity of this nation's constituencies, and include the following interests:

- State and local governments, including state membership entities
- Non-governmental organizations whose primary mission is

conservation and related scientific and advocacy activities
- American Indian/Alaska Native/Indigenous organizations
- Academia
- Other sectors, environmental justice organizations, private industry

Nominations should include a resume providing an adequate description of the nominee's qualifications, including information that would enable DOI to make an informed decision regarding meeting the membership requirements of the Council and to permit DOI to contact a potential member.

Members of the Council serve without compensation. However, while away from their homes or regular places of business, Council and subcommittee members engaged in Council or subcommittee business that the DFO approves may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by 5 U.S.C. 5703, in the same manner as persons employed intermittently in Federal Government service.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Certification Statement: I hereby certify that the Advisory Council for Climate Adaptation Science is necessary, in the public interest, and is in connection to the responsibilities of the Department of the Interior under Section 2 of the Reorganization Plan No. 3 of 1950 (64 Stat. 1262) as amended, and the Consolidated Appropriations Act of 2008, Public Law 110–161 Division F, Title I. The Council is established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. Appendix 2.

Authority: 5 U.S.C. Appendix 2.

Deb Haaland,

Secretary, Department of the Interior.

[FR Doc. 2022–26205 Filed 12–1–22; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[2231A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Pawnee Nation of Oklahoma Leasing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Pawnee Nation of Oklahoma Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into agricultural, business, residential, wind and solar, public, religious, educational, recreational, cultural, and other purposes leases without further BIA approval.

DATES: BIA issued the approval on November 22, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Carla Clark, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, *carla.clark@bia.gov,* (702) 484–3233.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal Leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Pawnee Nation of Oklahoma.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal Government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal Government pursuant to the HEARTH Act. Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self-government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the

Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal Government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Pawnee Nation of Oklahoma.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–26211 Filed 12–1–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[234 LLUT925000 L14400000.BJ0000 241A]

Filing of Plats of Survey; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing.

SUMMARY: The Bureau of Land Management (BLM) publishes this notice to inform the public of the official filing of the plats of survey of the lands described below in the BLM Utah State Office, Salt Lake City, Utah.

DATES: The plats of survey have been officially filed on the dates indicated below.

ADDRESSES: Written notices protesting a survey must be sent to the Utah State Director, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345.

FOR FURTHER INFORMATION CONTACT: Matthew J. Kurchinski, Chief Cadastral Surveyor for Utah, BLM, Branch of Geographic Sciences, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345, telephone (801) 539–4139, or email *mkurchin@blm.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. Please contact *mkurchinski@blm.gov* for more or for accommodation.

SUPPLEMENTARY INFORMATION: The plats of survey described below represent surveys executed at the request of the BLM, Bureau of Indian Affairs (BIA) and the National Park Service (NPS) and are necessary for the management of these lands. The lands surveyed are represented on the following plats of survey:

Salt Lake Meridian, Utah

T. 11 S, R. 17 W, Group No. 1341, prepared at the request of the BLM, was accepted September 23, 2022, and officially filed October 14, 2022.

T. 12 S, R. 17 W, Group No. 1341, prepared at the request of the BLM, was accepted September 23, 2022, and officially filed October 14, 2022.

T. 11 S, R. 18 W, Group No. 1341, prepared at the request of the BLM, was accepted September 23, 2022, and officially filed October 14, 2022.

T. 12 S, R. 18 W, Group No. 1341, prepared at the request of the BLM, was accepted September 23, 2022, and officially filed October 14, 2022.

T. 35 S, R. 3 E, Group No. 1452, prepared at the request of the BLM, was accepted April 4, 2022, and officially filed April 11, 2022.

T. 43 S, R. 3 E, Group No. 1429, prepared at the request of the NPS, was accepted September 30, 2022, and officially filed October 14, 2022.

T. 42 S, R. 4 E, Group No. 1429, prepared at the request of the NPS, was accepted September 30, 2022, and officially filed October 14, 2022.

T. 42 S, R. 5 E, Group No. 1429, prepared at the request of the NPS, was accepted September 30, 2022, and officially filed October 14, 2022.

T. 42 S, R. 15 E, Group No. 1468, prepared at the request of the BIA, was accepted September 26, 2022, and officially filed October 14, 2022.

T. 39 S, R. 22 E, Group No. 1472, prepared at the request of the BIA, was accepted September 30, 2022, and officially filed October 14, 2022.

T. 43 S, R. 25 E, Group No. 1462, prepared at the request of the BIA, was accepted September 23, 2022, and officially filed October 27, 2022.

Copies of the plats of survey and related field notes are available for public review in the BLM Utah State Office as a matter of information.

A person or party who wishes to protest one or more of the above surveys must file a written notice within 30 calendar days from the date of this publication with the Utah State Director, BLM, at the address listed in the **ADDRESSES** section, stating they wish to protest. The notice of protest must identify the plat(s) of survey the person or party wishes to protest. A statement of reasons for the protest, if not filed with the notice of protest, must be filed with the Utah State Director within 30 calendar days after the notice of protest is filed.

Before including your address, phone number, email address, or other

personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

Authority: 43 U.S.C. chap. 3.

Matthew J. Kurchinski,

Chief Cadastral Surveyor for Utah.

[FR Doc. 2022–26313 Filed 12–1–22; 8:45 am]

BILLING CODE 4310–25–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–545–546 and 731–TA–1291–1297 (Review), and 731–TA–808 (Fourth Review)]

Hot-Rolled Steel From Australia, Brazil, Japan, Netherlands, Russia, South Korea, Turkey, and the United Kingdom

Determination

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing duty order on hot-rolled steel flat products (''hot-rolled steel'') from South Korea and the antidumping duty orders on hot-rolled steel from Australia, Japan, Netherlands, Russia, South Korea, Turkey, and the United Kingdom would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. The Commission further determines that revocation of the countervailing duty and antidumping duty orders on hot-rolled steel from Brazil would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioners Rhonda K. Schmidtlein and Randolph J. Stayin determine that revocation of the countervailing duty orders on hot-rolled steel from Brazil and South Korea and the antidumping duty orders on hot-rolled steel from Australia, Brazil, Japan, Netherlands, Russia, South Korea, Turkey, and the United Kingdom would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on September 1, 2021 (86 FR 49057) and determined on December 6, 2021 that it would conduct full reviews (87 FR 3123, January 20, 2022). Notice of the scheduling of the Commission's reviews and of a public hearing 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** on June 16, 2022 (87 FR 36343). The Commission conducted its hearing on September 15, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on November 25, 2022. The views of the Commission are contained in USITC Publication 5380 (November 2022), entitled *Hot-Rolled Steel from Australia, Brazil, Japan, Netherlands, Russia, South Korea, Turkey and the United Kingdom: Investigation Nos. 701–TA–545–546 and 731–TA–1291–1297 (Review), and 731–TA–808 (Fourth Review).*

By order of the Commission.

Issued: November 25, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–26269 Filed 12–1–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–22–052]

Sunshine Act Meetings

Agency Holding the Meeting: United States International Trade Commission.

TIME AND DATE: December 5, 2022 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. 731–TA–540 and 541 (Fifth Review) (Certain Welded Stainless Steel Pipe from South Korea and Taiwan). The Commission currently is scheduled to complete and file its determinations and views of the Commission on December 13, 2022.
5. Outstanding action jackets: none.

CONTACT PERSON FOR MORE INFORMATION: Tyrell Burch, Management Analyst, 202–205–2595.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier notification of this meeting was not possible.

By order of the Commission.

Issued: November 29, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–26352 Filed 11–30–22; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–683 and 731–TA–1594–1596 (Preliminary)]

Paper File Folders From China, India, and Vietnam

Determinations

On the basis of the record [1] 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 paper file folders from China, India, and Vietnam provided for in subheading 4820.30.00 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 to be subsidized by the government of India.[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)

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 87 FR 67441 and 87 FR 67447, November 8, 2022.

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. 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.

Background

On October 12, 2022, the Coalition of Domestic Folder Manufacturers, Hastings, Minnesota and Naperville, Illinois 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 paper file folders from India and LTFV imports of paper file folders from China, India, and Vietnam. Accordingly, effective October 12, 2022, the Commission instituted countervailing duty investigation No. 701–TA–683 and antidumping duty investigation Nos. 731–TA–1594–1596 (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 October 19, 2022 (87 FR 63526). The Commission conducted its conference on November 2, 2022. 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 November 28, 2022. The views of the Commission are contained in USITC Publication 5389 (December 2022), entitled *Paper File Folders from China, India, and Vietnam: Investigation Nos. 701–TA–683 and 731–TA–1594–1596 (Preliminary).*

By order of the Commission.

Issued: November 28, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2022–26218 Filed 12–1–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1051E]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2023 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: The order is effective December 2, 2022.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedule I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

II. Background

The 2023 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2023, in order to provide for the estimated medical, scientific, research, and industrial needs of the U.S., lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On October 18, 2022, a notice titled ''Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023'' was published in the **Federal Register**. 87 FR 63091. This notice proposed the 2023 APQ for each basic class of controlled substance listed in schedules I and II and the 2023 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed APQ and the proposed AAN on or before November 17, 2022.

III. Comments Received

Within the public comment period, DEA received 357 comments from DEA registrants, chronic pain patients, patients with attention deficit/hyperactivity disorder, pain advocacy associations, professional associations, nurses, and others. The comments included concerns about potential opioid and stimulant drug shortages due to further quota reductions; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; one request for a public hearing; and comments not pertaining to DEA regulated activities. DEA restricted eight comments from public view due to confidential business information and/or confidential personal identifying information.

DEA's Regulatory Authority

Issue: DEA received comments that raised the question of whether DEA has the authority to regulate activities related to controlled substances, including the manufacture of Food and Drug Administration (FDA)-approved pharmaceutical products containing controlled substances.

DEA Response: The CSA, which was initially enacted in 1970 and has been amended several times, requires DEA to establish production quotas for certain controlled substances. 21 U.S.C. 826(a). In the CSA, Congress granted DEA (as delegated by the Attorney General under 21 U.S.C. 871(a)) the authority to promulgate ''rules and regulations''

relating to the ''registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals'' (21 U.S.C. 821), and to the ''registration and control of importers and exporters of controlled substances'' (21 U.S.C. 958(f)), as well as those ''necessary and appropriate for the efficient execution'' of the authorities granted by the CSA (21 U.S.C. 871(b)), among other provisions. In its findings, Congress acknowledged that many controlled substances ''have a useful and legitimate medical purpose.'' 21 U.S.C. 801(1).

Congress explicitly directed DEA to establish production quotas for controlled substances in schedule I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. 826(a). In recognition of FDA's related, but distinct, role in regulating pharmaceutical products, DEA's regulations require DEA to consider relevant information from FDA before DEA establishes the APQs. 21 CFR 1303.11(b)(6). For instance, FDA provides estimates of legitimate domestic medical needs. DEA considers this important information in proposing and revising the APQs.

Medication Shortages

Issue (Attention Deficit/Hyperactivity Disorder Medications [ADHD]): DEA received comments expressing general concerns regarding the ongoing shortages experienced with ADHD medications produced from amphetamine, dexmethylphenidate, methylphenidate, and lisdexamfetamine. Some commenters expressed a concern that patients will turn to black market or diverted products if they cannot obtain their prescribed medications through legitimate channels. Two manufacturers commented that the proposed quotas for lisdexamfetamine and methylphenidate may not be adequate to meet forecasted increases in foreign demand for exported products.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the estimated legitimate medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA sets APQs in a manner to provide for all legitimate medical purposes and for anticipated foreign demand. Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate drug shortages. Such efforts may include adjusting the APQ, adjusting individual domestic manufacturers' quotas, FDA's approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval.

Based on the data DEA considers in setting the APQs, including new FDA-approved drug products, as well as manufacturing issues that DEA considers under 21 CFR 1303.11(b)(7), DEA determined that the proposed APQs for amphetamine, dexmethylphenidate, methylphenidate, and lisdexamfetamine are sufficient to supply legitimate medical needs, reserve stocks, and export requirements for 2023.

Issue (Adderall Shortages): DEA received comments expressing general concerns regarding the ongoing shortages experienced with ADHD drug medications, specifically mentioning the branded drug product Adderall.

DEA Response: DEA is aware of patient reports that pharmacies are unable to fill prescriptions for their prescribed Adderall or one of its generic versions. DEA consults with FDA to set the APQ for amphetamine each calendar year. The majority of the manufacturers contacted by DEA and/or FDA have responded that they currently have sufficient quota to meet their contracted production quantities for legitimate patient medical needs. According to DEA's data, manufacturers have not fully utilized the APQ for amphetamine in support of domestic manufacturing, reserve stocks, and export requirements for the past three calendar years 2020, 2021 and 2022.

Based on this trend, DEA has not implemented an increase to the APQ for amphetamine at this time. Should the proposed established amphetamine APQ become inadequate to meet legitimate medical and scientific needs, sufficient reserve stocks, and export requirements, DEA has the authority and ability to adjust the APQ during the course of the year. 21 CFR 1303.13. DEA remains in communication with FDA regarding these shortage reports.

Issue (Opioid Shortage): There were commenters including pain associations and DEA-registered medical professionals that expressed concerns about the decrease in aggregate production quotas for opioids. These commenters alleged that decreases to the aggregate production quotas have resulted in a shortage of opioid medications, interfered with the treatment of patients, and impacted the quality of life for patients possibly leading to suicide.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. Although DEA sets the APQs for all schedule II opioids, there can be other factors and manufacturers' business practices that may contribute to a temporary shortage of controlled substances at the point of dispensation, despite the adequacy of the APQ set by DEA. In recent years, this has included plant shutdowns necessary to complete federally-mandated maintenance, labor shortages and a lack of production capacity. In such circumstances, DEA coordinates with FDA and can use the tools at its disposal under its CSA authority to prevent or alleviate drug shortages and ensure that patients are able to fill legitimate prescriptions for controlled substances without undue delay.

Issue (Hospital-Administered Injectable Opioid Shortage): DEA received many comments expressing concern that the proposed decreases to the production quotas of opioid controlled substances may result in shortages of drug products containing those controlled substances. These commenters alleged that decreases to the APQ have resulted in a shortage of injectable opioid medications and interfere with the treatment of patients.

A top U.S. manufacturer of generic sterile injectable medicines to U.S. hospitals and healthcare providers opined that DEA's prior production quota initially prevented manufacturers from addressing and solving the shortage. This commenter noted that today, hospitals are providing ongoing COVID–19 patient care and managing a backlog in elective surgeries. As a result, this commenter suggested that DEA reconsider the APQ reductions for schedule II opioids used in sterile injectable pain medicines.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the estimated legitimate medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA sets APQs in a manner to provide for all legitimate medical purposes. Opioid injectable products constitute less than 5% of their relevant APQ, therefore injectable shortages do not usually require changes to the relevant APQ. Based on the data that DEA is required to consider for setting the APQs, DEA has determined that the established APQs for opioids are sufficient to meet all legitimate needs for 2023. Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate

drug shortages. Such efforts may include adjusting the APQ, adjusting individual domestic manufacturers' quotas, FDA approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval. For example, in 2020, DEA adjusted its quota to increase the APQ for drug products containing fentanyl, hydromorphone, morphine, and codeine, and the assessments of annual needs for drug products containing pseudoephedrine and ephedrine. The increased production needs for those substances, which are used to treat patients in intensive care units and those on ventilators, was a result of the COVID–19 public health emergency. These actions were taken based on DEA's consultations with federal partners at the Department of Health and Human Services (HHS), drug manufacturers, drug distributors, and hospital associations. Similarly, in 2018, a domestic shortage of injectable hydromorphone was alleviated through FDA and DEA collaboration to identify other dosage-form manufacturers with injectable hydromorphone products in the market, and to determine whether those other dosage-form manufacturers had the capability to increase their production levels to meet legitimate patient need in a timely manner. When the agencies determined that the domestic manufacturers could not increase production adequately to meet legitimate patient need, DEA and FDA coordinated and used their respective regulatory authorities to allow for the limited importation of injectable hydromorphone into the United States.

Mental Health Concerns

Issue: DEA received a number of comments that raised the issue of mental health diagnoses and treatment becoming more widespread in the last few years. Some commenters expressed the concern that COVID–19 and social media are the reason more people are becoming aware of mental health issues and treatment options. These commenters stated that this awareness has resulted in the increased use of some medicines. One commenter stated that mental health is now being taken seriously, and access to mental health treatment has grown. This commenter further asked why we as a nation would decide to further limit treatment when the medications are already controlled substances, tightly tracked when being prescribed and dispensed, with laws in place to deter and prevent their misuse.

DEA Response: DEA is aware of the sensitivity surrounding the negative impact of COVID–19 on mental health and recognizes that mental health issues are a legitimate medical concern. When setting the APQ for controlled substances used in manufacturing the relevant FDA-approved drug products, DEA considers the legitimate medical need for these medicines, as determined in part through the number of legitimate prescriptions dispensed in prior years and anticipated to be dispensed in the coming quota year.

Supply Chain Disruption

Issue: DEA received several comments raising the concern of the potential cascade effect of limiting List 1 chemicals that are used to manufacture ADHD medications.

DEA Response: DEA is aware of the synthesis process used by the manufacturers of FDA-approved ADHD drug products. DEA considers the manufacturing yields and requirements of all of the controlled substances and List 1 chemicals in the synthesis pathways to ensure that the APQs allow for sufficient quantities at each step to meet the legitimate domestic medical, scientific, and industrial needs of the United States as well as export requirements.

Ryan Haight Act and Telemedicine Flexibilities

Issue: One commenter noted DEA's concern regarding the increased misuse of prescription stimulants among young adults. This commenter questioned why the agency does not end certain flexibilities granted in response to the COVID–19 pandemic that allow these substances to be prescribed and dispensed easily, in particular that which removed the in-person visit requirement generally mandated by the Ryan Haight Act.

DEA Response: On January 31, 2020, the Secretary of HHS declared a public health emergency with regard to COVID–19. Shortly thereafter, on March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under 21 U.S.C. 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States. This allowance was part of the Ryan Haight Act's amendments to the CSA. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, the telemedicine allowance under 21 U.S.C. 802(54)(D) applies. However, the majority of the issues pertaining to telemedicine are outside the scope of this rule, which is limited to setting APQs for Schedule I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Prescribing Hesitancy and Centers for Disease Control and Prevention (CDC) Guideline Changes

Issue: Many commenters, most of whom self-identified as chronic pain patients, expressed general concerns that DEA has not considered the *CDC Guidelines for Prescribing Opioids for Chronic Pain* which were revised in 2022. Commenters noted that the goal of the 2016 Guidelines was to decrease overdoses, but instead there has been an increase in overdoses nationwide of over 400 percent. A commenter opined that since the initial CDC Guidelines for Prescribing came out (in 2016), the chronic pain community has been targeted. Commenters stated that many chronic pain patients have been harmed, and some have died by suicide, due to the inability to get prescriptions because of the limits set by the CDC and reductions made by DEA. Many commenters mentioned that CDC recently revised its guidelines, allowing doctors to have more latitude in making treatment decisions to prescribe the appropriate dosage based on individual patient needs. A commenter stated that the 2022 Guidelines are supposed to reduce that harm of under-prescribing caused by the misapplication of the 2016 Guidelines. Commenters also stated that DEA needs to take the revised guidelines into consideration since there is no longer a hard limit to what a doctor can prescribe.

DEA Response: The CDC published the updated clinical practice guidelines for prescribing opioids for pain on November 3, 2022,[1] during the comment period for the 2023 Proposed APQ. 87 FR 70823. DEA will consider the impact of CDC's revised guidelines over time, in determining whether DEA may need to publish a revision to the currently proposed APQ values during the 2023 calendar year, when there is sufficient data to provide an understanding of the impact of the guidelines on the actual prescribing as practitioners seek to implement this guidance, provided that the prescriptions issued are for a legitimate medical purpose in the usual course of professional practice.

In addition, DEA's regulations do not impose a maximum limit on the amount of medication that may be prescribed on a single prescription. DEA has consistently emphasized and supported

[1] The CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022, accessed November 23, 2022 from *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

the authority of individual practitioners under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards, as outlined in DEA's policy statement published in the **Federal Register** on September 6, 2006, titled Dispensing Controlled Substances for the Treatment of Pain. 71 FR 52716.

Estimates of Diversion

Issue: DEA received numerous comments expressing concerns that DEA's reduction of quotas for pain-relieving controlled substances does not correlate to a reduction in overdose deaths. According to the commenters, overdose deaths in the United States continue to rise because of illegal fentanyl, heroin, and illegally manufactured pain pills, not from pharmaceutical medications prescribed to chronic pain patients. These commenters discussed that legitimate fentanyl is the least diverted among the covered controlled substances.

DEA Response: DEA is required to consider rates of overdose deaths pursuant to changes made by the SUPPORT Act. The Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act) (Pub. L. 115–271), codified at 21 U.S.C. 826(i), mandates that DEA estimate diversion for 5 controlled substances—fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. This estimation must consider the rates of overdose deaths, among other factors.

While overdose deaths may occur as a result of the use of illicit substances, DEA's quotas help prevent the misuse and diversion of pharmaceutical controlled substances. In this way, these quotas can reduce the occurrence of overdose and death from the use of legitimate controlled substances.

Issue: One commenter suggested that DEA's estimate of diversion for the five covered controlled substances underestimated actual diversion. The commenter stated nonmedical use of prescription opioids is not a legitimate medical purpose, but that DEA (allegedly) rejected this point in calculating diversion. The commenter also asserted that the estimate is incomplete because a number of states did not provide Prescription Drug Monitoring Program (PDMP) data for the five covered controlled substances.

DEA Response: The cited 2016 report [2] provides insightful information regarding the relationship between nonmedical prescription-opioid use and heroin use. However, it does not provided adequate data for DEA to modify the oxycodone diversion estimate. Additionally, as stated in the published 2023 Proposed APQ, DEA used available (hard) data at wholesale distribution and retail dispensing channels, *i.e.,* DEA's Theft/Loss Reports and state PDMP data.

The PDMP data submitted was adequate to allow DEA to draw reliable inferences about the population. The sample is large enough to allow DEA to accurately generalize the data to the whole population of the United States for use in the calculation of estimated national levels of diversion of the covered controlled substances.

Issue: Commenters raised questions regarding patient privacy issues relating to the PDMP data provided to DEA by states.

DEA Response: DEA requested and received anonymized, aggregated PDMP data from the states. No individual patient names, addresses, or other discrete, personally identifiable information was shared with DEA.

Percentage of Prescription Opioids Being Diverted

Issue: Multiple commenters stated that the APQs should not be reduced from calendar year 2022 APQ levels, given that less than 1 percent of prescription opioids are diverted. Several commenters calculated the percentage of estimated diversion for oxycodone and hydrocodone as 0.3 percent and 0.4 percent respectively.

DEA Response: DEA's regulations require it to consider numerous relevant factors in its determination of the APQ. In the October 18 **Federal Register** Notice, DEA did estimate that less than one percent of the total quantity of FDA-approved drug products containing the five specific opioid controlled substances were diverted. However, DEA also considers other relevant factors, as required by regulation, when determining the APQ. 21 U.S.C. 826(a), 21 CFR 1303.11(b). DEA's consideration of all of these relevant factors, including those discussed above such as legitimate prescriptions dispensed in prior years and anticipated to be dispensed in the coming quota year, resulted in the proposed 2023 APQ as published.

Schedule I Controlled Substances

Issue: Several commenters requested that DEA consider increasing production quotas for certain schedule I controlled substances, including: 5-methoxy-N,N-dimethyltryptamine (5–MeO–DMT), dimethyltryptamine (DMT), 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxymethamphetamine (MDMA), 2–CB, methylone, psilocyn, and psilocybin for research activities and clinical trials in the United States.

DEA also received comments from biotech companies requesting that DEA consider adjusting the relevant schedule I controlled substance APQ to allow for future pre-clinical and clinical trial research for post-traumatic stress disorder (PTSD), treatment-resistant depression, schizophrenia, and anxiety. One pharmaceutical company that intends to initiate clinical trials in 2023 for treatment of post-traumatic stress disorder (PTSD) suggested that DEA significantly increase the APQ for MDMA so that the company can initiate clinical development. Another biopharmaceutical company recommended a significant increase in the APQs for DMT and MDMA for scientific research into potential mental health treatments.

DEA Response: The APQs established today reflect DEA's estimates of the medical, scientific, research, and industrial needs of the United States for 2023, as well as lawful export requirements and the establishment and maintenance of reserve stocks. DEA can adjust the established APQs if these needs change. For instance, if DEA receives additional research protocols from DEA-registered researchers, or additional quota applications from DEA-registered manufacturers, DEA will consider revising the relevant APQ.

DEA did receive additional quota applications from DEA-registered manufacturers for 5–MeO–DMT, marijuana, psilocyn, psilocybin, MDMA, and MDA. DEA considered those applications accordingly, as discussed below. DEA has not received quota applications from DEA-registered manufacturers to support the requested changes in the APQ for the other controlled substances mentioned.

Issue: One company suggested that DEA involve representatives from indigenous communities in determining APQ for controlled substances that are potentially derived from plants traditionally used by indigenous groups in the Americas and beyond.

DEA Response: DEA has held discussions when requested with representatives of indigenous communities in the past and welcomes further engagement. The APQs and the individual manufacturing quotas are informed in part by the quota requests submitted by DEA-registered manufacturers of these substances, and the current needs of indigenous communities also may be reflected in the requests that DEA has received.

Schedule II Controlled Substances

Issue: DEA received comments suggesting that DEA evaluate and establish the APQ of oral solid and injectable dosage forms of medicines separately. The commenters specifically highlighted differences between dosage forms of certain opioids.

DEA Response: DEA sets APQ in a manner to include dispensing for legitimate medical purposes and, in turn, the APQ takes into consideration both injectable opioids and solid oral opioids to meet the estimated medical needs of the United States. The statute, at 21 U.S.C. 826(a)(2), allows but does not require DEA to grant aggregate and individual quotas in terms of dosage forms if the Agency determines that doing so will assist in avoiding the overproduction, shortage, or diversion of controlled substances. By issuing a single APQ covering all dosage forms of the basic class, rather than estimating APQ for each dosage form, DEA retains the flexibility to alleviate potential shortages and to react to unforeseen emergencies by adjusting the individual quotas granted to manufacturers under that APQ.

Comments From DEA-Registered Manufacturers

Issue: DEA received comments from five DEA-registered manufacturers regarding 10 different schedule I and II controlled substances, requesting that the proposed APQ for d-amphetamine (for conversion), dexmethylphenidate (for conversion), dexmethylphenidate (for sale), isomethadone, lisdexamfetamine, methylphenidate (for conversion), methylphenidate (for sale), noroxymorphone (for conversion), oripavine, and oxymorphone (for conversion) be established at sufficient levels to allow for manufacturers to meet medical and scientific needs.

DEA Response: DEA considered the comments for these specific controlled substances and determined that an increase from DEA's proposed APQs are not necessary at this time, as reflected below in the section titled Determination of 2023 Aggregate Production Quotas and Assessment of Annual Needs.

Request for Public Hearing

Issue: One pharmaceutical company requested a public hearing prior to publishing the Final Order to establish the initial 2023 APQ. This company requested a public hearing ''to correct the omissions and inaccurate diversion calculation in the 2023 oxycodone . . . Quota.'' The company asserted that these omissions led to an inaccurate diversion calculation for oxycodone and that the 2023 APQ requires a significant reduction from the 2022 APQ.

DEA Response: The decision whether to grant a hearing on the issues raised by the commenter lies solely within the discretion of the Administrator. 21 CFR 1303.11(c). This commenter is not a state. This request does not present any evidence that would lead to the conclusion that a hearing is necessary or warranted. DEA has addressed specific points raised by the commenter in Issues and Responses above.

Out of Scope Comments

DEA received comments that are outside the scope of this order. The comments were general in nature and raised issues of specific medical illnesses, and medical treatments. Other commenters suggested (1) making the United States a signatory to the *Nagoya Protocol and the Convention on Biological Diversity;* and (2) creating diversified categories for production and research on psilocybin-containing fungi fruiting bodies/sclerotia/liquid culture similar to cannabis (flower), fruiting body extract (akin to cannabis extract), and psilocybin and psilocyn separately as purified compounds (akin to delta-9-thc). Regarding this last suggestion, the commenter further suggested that the ''same system should then be replicated in regards to lophophora/mescaline, as well as other plants, fungi and lifeforms, which produce these compounds being used in whole or closer to whole ways.'' These comments do not impact the analysis involved in establishing the 2023 APQ.

IV. Determination of 2023 Aggregate Production Quotas and Assessment of Annual Needs

In determining the established 2023 aggregate production quotas and assessment of annual needs, DEA has considered the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a). These factors include, but are not limited to, the 2022 manufacturing quotas, current 2022 sales and inventories, anticipated 2023 export requirements, industrial use, additional applications for 2023 quotas, and information on research and product development requirements.

On November 17, 2022, DEA published a final order placing amineptine in schedule I of the CSA (87 FR 68895), making all regulatory controls pertaining to the schedule I controlled substances applicable to the manufacture of this substance, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303. This final order establishes an aggregate production quota for this substance.

Based on all of the above, the Administrator establishes the 2023 APQ for 2–CB, 5–MEO–DMT, MDA, MDMA, methylone, psilocyn, d-methamphetamine (for sale), fentanyl, and 4-anilino-n-phenethyl-4-piperidine (ANPP), at higher levels than was proposed.

DEA has determined that the proposed APQs for d-amphetamine (for conversion), dexmethylphenidate (for conversion), dexmethylphenidate (for sale), isomethadone, lisdexamphetamine, methylphenidate (for conversion), methylphenidate (for sale), and noroxymorphone (for conversion) are sufficient to provide for the 2023 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these APQ at the same amounts as proposed.

The Administrator establishes the 2023 AAN for ephedrine (for conversion) at a higher level than was proposed.

Estimates of Diversion Pursuant to the SUPPORT Act

As specified in the proposal, and as required by 21 U.S.C. 826(i), DEA calculated a national diversion estimate for each of the covered controlled substances.

This data, which remains unchanged, was published in the *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023.*

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2023 APQ for the following schedule I and II controlled substances and the 2023 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2023 quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]-pyrrolidine	20
1-(1-Phenylcyclohexyl)-pyrrolidine	30

Basic class	Established 2023 quotas (g)
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]-piperidine	15
2′-fluoro 2-fluorofentanyl	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)-ethanamine (2C-H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxypheny-l)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxypheny-l)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxypheny-l]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxypheny-l]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	12,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	5,200
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4,4′-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4-CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4F-MDMB-BINACA	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4′-Methyl acetyl fentanyl	30
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5F-AB-PINACA ; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F-CUMYL-P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25
5F-CUMYL-PINACA	25
5F-EDMB-PINACA	25
5F-MDMB-PICA	25
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25
5-Fluoro-PB-22; 5F-PB-22	25
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	11,000
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
All other tetrahydrocannabinol	15,000
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Amineptine	30
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
beta-Hydroxy-3-methylfentanyl	30
beta-Hydroxyfentanyl	30
beta-Hydroxythiofentanyl	30

Basic class	Established 2023 quotas (g)
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9-THC	384,460
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	653,548
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flunitazene	30
FUB-144	25
FUB-AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
Isotonitazine	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA-(AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Metodesnitazene	30
Metonitazene	30
Marijuana	6,675,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	1,200
Methaqualone	60
Methcathinone	25
Methoxetamine	30
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Nicocodeine	25
Nicomorphine	25
N-methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyryl fentanyl	30
Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	8,000
Psilocyn	12,000
Racemoramide	25
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
Thiofuranyl fentanyl	30
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30
Valeryl fentanyl	25

Schedule II

1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,874
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100

Basic class	Established 2023 quotas (g)
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	1,085,024
Codeine (for sale)	21,003,397
D-amphetamine (for sale)	21,200,000
D,l-amphetamine	21,200,000
d-amphetamine (for conversion)	20,000,000
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	4,200,000
Dextropropoxyphene	35
Dihydrocodeine	132,658
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	731,452
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,239,822
Hydromorphone	1,994,117
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	26,500,000
Meperidine	681,289
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	47,000
l-methamphetamine	587,229
Methylphenidate (for sale)	41,800,000
Methylphenidate (for conversion)	15,300,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,458,460
Morphine (for sale)	21,747,625
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	53,840,608
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	516,351
Pentobarbital	33,843,337
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	11,941,416
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	41,100
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator also establishes APQ for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2023 APQ and AAN as needed.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 29, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022-26351 Filed 11-30-22; 11:15 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1121]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Alm Management

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 31, 2023.

ADDRESSES: DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice

does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on October 25, 2022, Alm Management, 7460 Varna Avenue, North Hollywood, California 91605, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2022–26208 Filed 12–1–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1122]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Attitude Wellness

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 31, 2023.

ADDRESSES: DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on October 3, 2022, Attitude Wellness, 9741 South Industrial Drive, Evart, Michigan 49631, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2022–26207 Filed 12–1–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0086]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of and Renewal of Previously Approved Collection; Comments Requested; Electronic Applications for the Attorney Student Loan Repayment Program

AGENCY: Office of Attorney Recruitment and Management, Justice Management Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of Attorney Recruitment and Management (OARM), Justice Management Division, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until January 31, 2023.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Deana Willis, Assistant Director, Office of Attorney Recruitment and Management, 450 5th Street NW, Suite 10200, Washington, DC 20530; *Deana.Willis@usdoj.gov;* (202) 514–8902.

SUPPLEMENTARY INFORMATION: Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Office of Attorney Recruitment and Management, 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;
- Evaluate whether, and if so, how, the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of information collection:* Revision and renewal of a Currently Approved Collection.

2. *The title of the form/collection:* Electronic Applications for the Attorney Student Loan Repayment Program.

3. *The agency form number, if any, and the applicable component of the department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of Attorney Recruitment and Management, Justice Management Division, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Other: None. The Department of Justice Attorney Student Loan Repayment Program (ASLRP) is an agency recruitment and retention incentive program based on 5 U.S.C. 5379, as amended, and 5 CFR part 537. Individuals currently employed as a DOJ attorney and incoming hires for attorney positions within the Department may request consideration for the ASLRP. The Department selects new participants during an annual open season each spring and renews current beneficiaries (DOJ employees) who remain qualified for these benefits, subject to availability of funds. There are three forms in the collection: an initial request for consideration; a justification form, and a loan continuation form. The ''initial request'' form is submitted voluntarily, by current DOJ employees as well as by incoming DOJ attorney hires who, if selected, do not receive benefits until they are a DOJ employee. Renewal requests, submitted by only by current DOJ employees, use a related form not subject to the Paperwork Reduction Act—no non-employees would qualify.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* The Department anticipates about 150 respondents annually will complete the new request form and justification form and apply for participation in the ASLRP. Of those, an average of 21 are incoming attorney hires who have not yet entered on duty with the DOJ. The remaining respondents are current DOJ employees. It is estimated that each new request (including justification) will take two (2) hours to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated burden associated with this collection is 42 hours. It is estimated that new applicants will take 2 hours to complete the request form and justification, and, as needed, the loan continuation form. The burden hours for collecting respondent data, 42 hours, are calculated as follows: 21 new respondents who are members of the public × 2 hours = 42 hours.

If additional information is required, please contact: Robert Houser, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, U.S. Department of Justice, Two Constitution Square, 145 N Street NE, Room 3E.206, Washington, DC 20530.

Dated: November 29, 2022.

Robert J. Houser,

Department Clearance Officer for PRA, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.

[FR Doc. 2022–26261 Filed 12–1–22; 8:45 am]

BILLING CODE 4410–PB–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–01; NRC–2021–0122]

GE-Hitachi Nuclear Energy Americas, LLC; Morris Operation Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Subsequent license renewal; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a subsequent renewed license to GE-Hitachi Nuclear Energy Americas, LLC (GEH) for Special Nuclear Materials (SNM) License No. SNM–2500 for the possession, transfer, and storage of radioactive material at the Morris Operation Independent Spent Fuel Storage Installation (ISFSI) (GEH–MO). GEH–MO is located in Grundy County, Illinois, near Morris, Illinois. The subsequent renewed license authorizes operation of GEH–MO in accordance with the provisions of the subsequent renewed license and its technical

specifications. The subsequent renewed license expires on May 31, 2042.

DATES: The license referenced in this document is available as of November 22, 2022.

ADDRESSES: Please refer to Docket ID NRC–2021–0122 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–2021–0122. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov*. For technical questions, contact the individual listed in the ''For Further Information Contact'' section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov*. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. 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 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kristina L. Banovac, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7116, email: *Kristina.Banovac@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Discussion

Based upon the application dated June 30, 2020, as supplemented on February 26, 2021, March 19, 2021, March 24, 2021, January 27, 2022, and May 12, 2022, the NRC has issued a subsequent renewed license to the licensee for GEH–MO, located in in Grundy County, Illinois, near Morris, Illinois. The subsequent renewed license SNM–2500 authorizes and requires operation of GEH–MO in accordance with the provisions of the subsequent renewed license and its technical specifications. The subsequent renewed license will expire on May 31, 2042.

The licensee's application for a renewed license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the NRC's rules and regulations. The NRC has made appropriate findings as required by the Act and the NRC's regulations in chapter 1 of title 10 of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the subsequent renewed license. The agency afforded an opportunity for a hearing in the Notice of Opportunity for a Hearing published in the **Federal Register** on June 30, 2021 (86 FR 34790). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a safety evaluation report for the subsequent renewal of the ISFSI license and concluded, based on that evaluation, the ISFSI will continue to meet the regulations in 10 CFR part 72. The NRC staff also prepared an environmental assessment and finding of no significant impact for the subsequent renewal of this license, which were published in the **Federal Register** on November 17, 2022 (87 FR 69053). The NRC staff's consideration of the impacts of continued storage of spent nuclear fuel (as documented in NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'') was included in the environmental assessment. The NRC staff concluded that subsequent renewal of this ISFSI license will not have a significant impact on the quality of the human environment.

II. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	ADAMS Accession No.
Licensee's Renewal Application, dated June 30, 2020	ML20182A699 (Package).
Response to Request for Supplemental Information, dated February 26, 2021	ML21057A119 (Package).
Response to Request for Clarification, dated March 19, 2021	ML21085A859.
Submittal of Updated Consolidated Safety Analysis Report, dated March 24, 2021	ML21083A200 (Package).
Response to Request for Additional Information, dated January 27, 2022	ML22027A516.
Response to Request for Clarification, dated May 12, 2022	ML22132A072.
Special Nuclear Materials License No. SNM–2500	ML22242A017 and ML22242A018.
SNM–2500 Technical Specifications	ML22242A034
NRC Safety Evaluation Report	ML22234A257.
NRC Environmental Assessment	ML22270A269.
NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'' Vol. 1	ML14196A105.
NUREG–2157, ''Generic Environmental Impact Statement for Continued Storage of Spent Fuel'' Vol. 2	ML14196A107.

Dated: November 28, 2022.

For the Nuclear Regulatory Commission.

Yoira K. Diaz-Sanabria,

Chief, Storage and Transportation Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–26230 Filed 12–1–22; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 5 CFR 837.103, Reemployment of Annuitants, 3206–0211

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an existing information collection request, Reemployment of Annuitants.

DATES: Comments are encouraged and will be accepted until January 3, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *http://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 or fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street, NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0211) was previously published in the **Federal Register** on February 24, 2022, at 87 FR 10394, allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

OPM regulations under 5 CFR 837.103 require employing agencies to collect certain information from reemployed annuitants on or before the date the employing agency appoints a reemployed annuitant to a Government position. Agencies need to collect timely information regarding the type and amount of annuity being received so the correct rate of pay can be determined. Agencies provide this information to OPM so a determination can be made whether the reemployed annuitant's retirement annuity must be terminated or suspended upon reemployment.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: 5 CFR 837.103, Notice.

OMB Number: 3206–0211.

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 3,000.

Estimated Time per Respondent: 5 minutes.

Total Burden Hours: 250.

U.S. Office of Personnel Management.

Kellie Cosgrove Riley,

Director, Office of Privacy and Information Management.

[FR Doc. 2022–26301 Filed 12–1–22; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96396; File No. SR–BX–2022–023]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FINRA Fees

November 28, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 21, 2022, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX's Pricing Schedule at Equity 7, Section 30, Regulatory, Registration and Processing Fees, to reflect adjustments to FINRA Registration Fees and Fingerprinting Fees.[3]

While the changes proposed herein are effective upon filing, the Exchange has designated the additional processing of each initial or amended Form U4, Form U5 or Form BD and electronic Fingerprint Processing Fees to become operative on January 2, 2023. Additionally, the Exchange designates that the FINRA Annual System Processing Fee Assessed only during Renewals become operative on January 2, 2024.[4] The amendments to the paper Fingerprint Fees are immediately effective.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This proposal amends Equity 7, Section 30, Regulatory, Registration and Processing Fees, to reflect adjustments to FINRA Registration Fees and Fingerprinting Fees.[5] The FINRA fees are collected and retained by FINRA via Web CRD for the registration of employees of BX members that are not FINRA members (''Non-FINRA

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This rule change impacts FINRA fees for members who trade equity and options products on BX as all BX Options Participants are required to be BX members.

[4] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592(October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust FINRA Fees To Provide Sustainable Funding for FINRA's Regulatory Mission).

[5] FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

members''). The Exchange is merely listing these fees on its Pricing Schedule. The Exchange does not collect or retain these fees.

The Exchange proposes to amend: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the $15 Second Submission (Electronic) Fingerprint Processing Fee to $20. Each of these fees are listed within BX Equity 7, Section 30. These amendments are being made in accordance with a FINRA rule change to adjust to its fees.[6]

The Exchange also proposes to amend the following Fingerprint Fees: (1) the $29.50 Initial Submission (Electronic) fee to $31.25 [7]; (2) the $44.50 Initial Submission (Paper) fee to $41.25 [8]; (3) the $29.50 Third Submission (Electronic) fee to $31.25 [9]; and (4) the $44.50 Third Submission (Paper) fee to $41.25.[10] Specifically, today, the FBI fingerprint charge is $11.25 [11] and the FINRA electronic Fingerprint Fee will increase from $15 to $20 in 2023.[12] While FINRA did not amend the paper Fingerprint Fee, previously the FBI Fee was reduced from $14.50 to $11.25.[13] The paper Fingerprint Fees are not currently reflecting the amount assessed by FINRA. The amendment to the paper Fingerprint Fees will conform these fees with those of FINRA.

The FINRA Web CRD Fees are user-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[15] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes it is reasonable to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees [16] because the proposed fees are identical to those adopted by FINRA for use of Web CRD for disclosure and the registration of FINRA members and their associated persons.

These costs are borne by FINRA when a Non-FINRA member uses Web CRD. The Exchange's rule text will reflect the current registration and electronic fingerprint rates that will be assessed by FINRA as of January 2, 2023 for the additional processing of each initial or amended Form U4, Form U5 or Form BD and Second Submission (Electronic) Fingerprint Processing Fee and the registration rates that will be assessed by FINRA as of January 2, 2024 for the FINRA Annual System Processing Fee Assessed only during Renewals.[17]

The Exchange believes it is reasonable to correct the paper Fingerprint Fees to reflect the reduced FBI Fee of $11.25.[18] The amendments to the paper Fingerprint Fees will provide all Exchange members with the correct Fingerprint Fees.

The Exchange believes it is equitable and not unfairly discriminatory to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees [19] because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. Similarly, the Exchange believes it is equitable and not unfairly discriminatory to correct the paper Fingerprint Fees to reflect the reduced FBI Fee of $11.25 [20] because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that its proposal to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees [21] does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. The proposal will reflect the fees that will be assessed by FINRA to all members who register or require fingerprints as of January 2, 2023 and January 2, 2024, respectively.

Similarly, the Exchange believes it does not impose an undue burden on competition to correct the paper Fingerprint Fees to reflect the reduced

[6] *See* note 4. FINRA noted in its rule change that it was adjusting its fees to provide sustainable funding for FINRA's regulatory mission.

[7] This fee includes a $20.00 FINRA fee and $11.25 FBI fee). *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[8] This fee includes a $30 FINRA Fee and a $11.25 FBI Fee. *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[9] This fee includes a $20.00 FINRA fee and $11.25 FBI fee). *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[10] This fee includes a $30 FINRA Fee and a $11.25 FBI Fee. *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[11] *See* Securities Exchange Act Release No. 67247 (June 25, 2012) 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository) (''2012 Rule Change'')

[12] *See* note 4.

[13] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4) and (5).

[16] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

[17] *See* note 4.

[18] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[19] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

[20] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[21] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

FBI Fee of $11.25 because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2022–023 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–BX–2022–023. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2022–023 and should be submitted on or before December 23,2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–26233 Filed 12–1–22; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(A)(ii).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96393; File No. SR–NASDAQ–2022–067]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FINRA Fees

November 28, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 21, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Nasdaq's Pricing Schedule at Equity 7, Section 30, Regulatory, Registration and Processing Fees, to reflect adjustments to FINRA Registration Fees and Fingerprinting Fees.[3]

While the changes proposed herein are effective upon filing, the Exchange has designated the additional processing of each initial or amended Form U4, Form U5 or Form BD and electronic Fingerprint Processing Fees to become operative on January 2, 2023. Additionally, the Exchange designates that the FINRA Annual System Processing Fee Assessed only during Renewals become operative on January 2, 2024.[4] The amendments to the paper Fingerprint Fees are immediately effective.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This proposal amends Equity 7, Section 30, Regulatory, Registration and Processing Fees, to reflect adjustments to FINRA Registration Fees and

[3] This rule change impacts FINRA fees for members who trade equity and options products on Nasdaq as all NOM Participants are required to be Nasdaq members.

[4] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust FINRA Fees To Provide Sustainable Funding for FINRA's Regulatory Mission).

Fingerprinting Fees.[5] The FINRA fees are collected and retained by FINRA via Web CRD for the registration of employees of Nasdaq members that are not FINRA members (''Non-FINRA members''). The Exchange is merely listing these fees on its Pricing Schedule. The Exchange does not collect or retain these fees.

The Exchange proposes to amend: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the $15 Second Submission (Electronic) Fingerprint Processing Fee to $20. Each of these fees are listed within Nasdaq Equity 7, Section 30. These amendments are being made in accordance with a FINRA rule change to adjust to its fees.[6]

The Exchange also proposes to amend the following Fingerprint Fees: (1) the $29.50 Initial Submission (Electronic) fee to $31.25;[7] (2) the $44.50 Initial Submission (Paper) fee to $41.25;[8] (3) the $29.50 Third Submission (Electronic) fee to $31.25;[9] and (4) the $44.50 Third Submission (Paper) fee to $41.25.[10] Specifically, today, the FBI fingerprint charge is $11.25[11] and the FINRA electronic Fingerprint Fee will increase from $15 to $20 in 2023.[12] While FINRA did not amend the paper Fingerprint Fee, previously the FBI Fee was reduced from $14.50 to $11.25.[13] The paper Fingerprint Fees are not currently reflecting the amount assessed by FINRA. The amendment to the paper Fingerprint Fees will conform these fees with those of FINRA.

The FINRA Web CRD Fees are user-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[15] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes it is reasonable to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees[16] because the proposed fees are identical to those adopted by FINRA for use of Web CRD for disclosure and the registration of FINRA members and their associated persons.

These costs are borne by FINRA when a Non-FINRA member uses Web CRD. The Exchange's rule text will reflect the current registration and electronic fingerprint rates that will be assessed by FINRA as of January 2, 2023 for the additional processing of each initial or amended Form U4, Form U5 or Form BD and Second Submission (Electronic) Fingerprint Processing Fee and the registration rates that will be assessed by FINRA as of January 2, 2024 for the FINRA Annual System Processing Fee Assessed only during Renewals.[17]

The Exchange believes it is reasonable to correct the paper Fingerprint Fees to reflect the reduced FBI Fee of $11.25.[18] The amendments to the paper Fingerprint Fees will provide all Exchange members with the correct Fingerprint Fees.

The Exchange believes it is equitable and not unfairly discriminatory to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees[19] because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. Similarly, the Exchange believes it is equitable and not unfairly discriminatory to correct the paper Fingerprint Fees to reflect the reduced FBI Fee of $11.25[20] because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that its proposal to increase: (1) the $110 fee for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification or one or more disclosure events or proceedings to $155; (2) the $45 FINRA Annual System Processing Fee Assessed only during Renewals to $70; and (3) the electronic Fingerprint Fees from $15 to $20 in accordance with an adjustment to FINRA's fees[21] does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly

[5] FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

[6] *See* note 4. FINRA noted in its rule change that it was adjusting its fees to provide sustainable funding for FINRA's regulatory mission.

[7] This fee includes a $20.00 FINRA fee and $11.25 FBI fee). *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[8] This fee includes a $30 FINRA Fee and a $11.25 FBI Fee. *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[9] This fee includes a $20.00 FINRA fee and $11.25 FBI fee). *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[10] This fee includes a $30 FINRA Fee and a $11.25 FBI Fee. *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[11] *See* Securities Exchange Act Release No. 67247 (June 25, 2012) 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository) (''2012 Rule Change'')

[12] *See* note 4.

[13] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4) and (5).

[16] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

[17] *See* note 4.

[18] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[19] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

[20] *See* 2012 Rule Change at note 6. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

[21] The $20 FINRA Fee is in addition to the $11.25 FBI Fee except for the second fingerprint transaction.

discriminatory manner. The proposal will reflect the fees that will be assessed by FINRA to all members who register or require fingerprints as of January 2, 2023 and January 2, 2024, respectively.

Similarly, the Exchange believes it does not impose an undue burden on competition to correct the paper Fingerprint Fees to reflect the reduced FBI Fee of $11.25 because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–067 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–NASDAQ–2022–067. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–067 and should be submitted on or before December 23, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–26232 Filed 12–1–22; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(A)(ii).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96394; File No. 4–698]

Joint Industry Plan; Notice of Filing of Partial Amendment No. 1 to an Amendment to the National Market System Plan Governing the Consolidated Audit Trail

November 28, 2022.

On May 13, 2022, the Operating Committee for Consolidated Audit Trail, LLC (''CAT LLC''), on behalf of the following parties to the National Market System Plan Governing the Consolidated Audit Trail (the ''CAT NMS Plan'' or ''Plan''):[1] BOX Exchange LLC; Cboe BYX Exchange, Inc.; Cboe BZX Exchange, Inc.; Cboe EDGA Exchange, Inc.; Cboe EDGX Exchange, Inc.; Cboe C2 Exchange, Inc.; Cboe Exchange, Inc.; Financial Industry Regulatory Authority, Inc.; Investors Exchange LLC; Long-Term Stock Exchange, Inc.; MEMX, LLC; Miami International Securities Exchange LLC; MIAX Emerald, LLC; MIAX PEARL, LLC; Nasdaq BX, Inc.; Nasdaq GEMX, LLC; Nasdaq ISE, LLC; Nasdaq MRX, LLC; Nasdaq PHLX LLC; The NASDAQ Stock Market LLC, New York Stock Exchange LLC; NYSE American LLC; NYSE Arca, Inc.; NYSE Chicago, Inc.; and NYSE National, Inc. (collectively, the ''Participants,'' ''self-regulatory organizations,'' or ''SROs'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') pursuant to Section 11A(a)(3) of the Securities Exchange Act of 1934 (''Exchange Act''),[2] and Rule 608 thereunder,[3] a proposed amendment to the CAT NMS Plan (''Proposed Amendment'') to implement a revised funding model (''Executed Share Model'') for the consolidated audit trail (''CAT'') and to establish a fee schedule for Participant CAT fees in accordance with the Executed Share Model (''Proposed Participant Fee Schedule'').[4] The Proposed Amendment was published for comment in the **Federal Register** on June 1, 2022.[5] On August 30, 2022, pursuant to Rule 608(b)(2)(i) of Regulation NMS,[6] the Commission instituted proceedings to determine

[1] The CAT NMS Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Exchange Act and the rules and regulations thereunder. *See* Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016) (''CAT NMS Plan Approval Order''). The CAT NMS Plan functions as the limited liability company agreement of the jointly owned limited liability company formed under Delaware state law through which the Participants conduct the activities of the CAT (''Company''). On August 29, 2019, the Participants replaced the CAT NMS Plan in its entirety with the limited liability company agreement of a new limited liability company named Consolidated Audit Trail, LLC (''CAT LLC''), which became the Company. The latest version of the CAT NMS Plan is available at *https://catnmsplan.com/about-cat/cat-nms-plan.*

[2] 15 U.S.C. 78k–1(a)(3).

[3] 17 CFR 242.608.

[4] *See* Letter from Michael Simon, CAT NMS Plan Operating Committee Chair, to Vanessa Countryman, Secretary, Commission (May 13, 2022).

[5] *See* Securities Exchange Act Release No. 94984 (May 25, 2022), 87 FR 33226 (June 1, 2022) (''Notice'' or ''Proposing Release''). Comments received in response to the Notice can be found on the Commission's website at *https://www.sec.gov/comments/4-698/4-698-a.htm.*

[6] 17 CFR 242.608(b)(2)(i).

whether to disapprove the Proposed Amendment.[7]

On November 16, 2022, CAT LLC submitted a letter (the ''CAT LLC Letter'') to propose a partial amendment of the Proposed Amendment (''Partial Amendment No. 1'') and to respond to the Commission's solicitation of comments in the OIP and comments received on the OIP.[8] Sections I and II below contains an executive summary of Partial Amendment No. 1 and a description of the proposed revisions to the Proposed Amendment, which were substantially prepared by CAT LLC on behalf of the Participants.[9] The Commission is publishing this notice to solicit comments on Partial Amendment No. 1 from interested persons.

I. Executive Summary

CAT LLC proposes to amend the CAT NMS Plan [10] to implement a revised funding model—Executed Share Model—for the consolidated audit trail (''CAT'') and to establish a fee schedule for Participant CAT fees in accordance with the Executed Share Model. The SEC published the Proposed Amendment for comment on May 25, 2022.[11] After considering the comments provided in response to the Proposed Amendment, the issues discussed in the OIP and comments submitted in response to the OIP,[12] CAT LLC continues to believe that the Executed Share Model satisfies the applicable requirements of the Exchange Act as well as the funding principles and other requirements of the CAT NMS Plan, as proposed to be revised.

The Executed Share Model would provide reasonable fees that are equitably allocated, not unfairly discriminatory, and do not impose an undue burden on competition, in that the model reflects a reasonable effort to allocate costs based on the extent to which different CAT Reporters participate in and benefit from the equities and options markets. Moreover, the Executed Share Model would be consistent with past fee structures that have been approved by the Commission. It also is transparent, would be relatively easy to calculate and administer, and is designed to not have an impact on market activity because it is neutral as to the location and manner of execution. CAT LLC has gone through an extensive process of evaluating and seeking comment on various funding models since the inception of CAT. As the Commission is aware, the Exchange Act does not require CAT LLC to demonstrate that the Executed Share Model is *superior to any other potential proposal.* Instead, CAT LLC must demonstrate that the Executed Share Model is *consistent with the Exchange Act and the rules and regulations thereunder.* CAT LLC believes that the Executed Share Model satisfies the requirements of the Exchange Act and should be approved by the Commission.

CAT LLC, however, proposes to amend the Proposed Amendment to provide additional detail and clarity on the Executed Share Model in response to the OIP. Specifically, CAT LLC proposes to amend the Proposed Amendment by making changes summarized below and discussed in detail in Section II of this letter. In addition to these proposed revisions, CAT LLC responds to each of the other issues raised in the SEC's OIP in Section III of the CAT LLC Letter.[13]

(1) CAT LLC proposes to make the following general changes to the description of the Executed Share Model as set forth in the Proposed Amendment:

- Restructure the description of the Executed Share Model in the CAT NMS Plan to fully describe the process for calculating the Historical CAT Assessment and the CAT Fees related to Prospective CAT Costs, rather than describing certain aspects of the Executed Share Model in the Participant fee schedule or in the Participant fee filings related to the Industry Member fees. (Proposed Section 11.3 of the CAT NMS Plan)
- Impose the payment obligation on the executing broker for the buyer for the transaction (''EBB'') instead of the clearing broker for the buyer for the transaction (''CBB''), and impose the payment obligation on the executing broker for the seller for the transaction (''EBS''), rather than the clearing broker for the seller for the transaction (''CBS''). (Proposed Sections 11.3(a)(iii)(A) and (b)(iii)(A) of the CAT NMS Plan)
- Provide for the use of a twelve-month lookback, rather than a six-month lookback, for the calculation of equivalent executed share volume projections. (Proposed Sections 11.3(a)(i)(D) and (b)(i)(E) of the CAT NMS Plan)
- Amend the CAT funding principles to clarify that the CAT Fees with regard to Prospective CAT Costs and the Historical CAT Assessment are intended to be cost-based fees—that is, the fees are designed to recover the cost of the creation, implementation and operation of the CAT. (Proposed 11.2(c) of the CAT NMS Plan)

(2) In addition to the above general changes, CAT LLC proposes to amend the description of CAT Fees related to Prospective CAT Costs as follows:

- Require the calculation of a Fee Rate for the CAT Fee twice a year, once at the beginning of the year and once during the year, and to require the Participants to file with the SEC pursuant to Section 19(b) of the Exchange Act the CAT Fees to be charged to Industry Members calculated using the Fee Rates calculated twice a year. (Proposed Section 11.3(a)(i)(A)(I) and (II) of the CAT NMS Plan)
- Explain that CAT Fees will remain in effect until the Operating Committee approves a new Fee Rate and the CAT Fees with the new Fee Rate are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act. (Proposed Section 11.3(a)(i)(A)(III) of the CAT NMS Plan)
- Provide additional detail regarding the categories included in the CAT budget: technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and such other categories as determined by the Operating Committee. (Proposed Section 11.1(a)(i) of the CAT NMS Plan)
- Describe the size of the reserve as not more than 25% of the annual budget, and state that, to the extent collected CAT Fees exceed CAT costs, including the reserve of 25% of the annual budget, such surplus shall be used to offset future fees. (Proposed Section 11.1(a)(ii) of the CAT NMS Plan)

[7] *See* Securities Exchange Act Release No. 95634 (Aug. 30, 2022), 87 FR 54558 (Sept. 6, 2022) (''OIP''). Comments received in response to the OIP can be found on the Commission's website at *https://www.sec.gov/comments/4-698/4-698-a.htm.*

[8] *See* Letter from Michael Simon, CAT NMS Plan Operating Committee Chair, to Vanessa Countryman, Secretary, Commission (Nov. 15, 2022) (''Partial Amendment No. 1'').

[9] This notice includes only Sections I and II of the CAT LLC Letter, which describe the changes proposed by Partial Amendment No. 1. The full text of the CAT LLC Letter, which includes the Participants responses to the OIP in Section III thereof, is available on the Commission's website at *https://www.sec.gov/comments/4-698/4-698-a.htm.*

[10] The twenty-five Participants of the CAT NMS Plan are: BOX Exchange LLC, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe Exchange, Inc., Financial Industry Regulatory Authority, Inc. (''FINRA''), Investors Exchange LLC, Long-Term Stock Exchange, Inc., MEMX LLC, Miami International Securities Exchange LLC, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The NASDAQ Stock Market LLC, New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc. and NYSE National, Inc.

[11] *See* Notice, *supra* note 5.

[12] Letter from Ellen Greene, Managing Director, Equities and Options Market Structure, SIFMA, to Vanessa Countryman, Secretary, SEC (Oct. 7, 2022) (''SIFMA Letter'').

[13] *See supra* note 9.

• Clarify that Participants will be required to pay the CAT Fees approved by the Operating Committee only if such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act. (Proposed Section 11.3(a)(ii)(B) of the CAT NMS Plan)

• Require the fee filings pursuant to Section 19(b) of the Exchange Act for CAT Fees related to Prospective CAT Costs to provide details regarding the calculation of the fee, including the Fee Rate, budget, projected volume, and the reconciliation of the budget to the fees. (Proposed Section 11.3(a)(iii)(B) of the CAT NMS Plan)

(3) Furthermore, CAT LLC proposes to describe in detail the Historical CAT Assessment in the CAT NMS Plan by making the following revisions to the CAT NMS Plan:

• Describe the Historical CAT Assessment as described in the Proposed Amendment in the CAT NMS Plan in detail, including that the Historical CAT Assessment applies to Industry Members, how it will be used to repay the Participants, the manner of calculating the Historical Fee Rate, a description of the calculation of the Historical CAT Assessment, and a description of the fee filings under Section 19(b) of the Exchange Act for the Historical CAT Assessment. (Proposed Section 11.3(b) of the CAT NMS Plan)

• State that the length of the Historical Recovery Period used in calculating the Historical Fee Rate will not be less than 24 months or more than five years, and that the Historical CAT Assessment calculated using the Historical Fee Rate will remain in effect until all Historical CAT Costs are collected. (Proposed Section 11.3(b)(i)(D) of the CAT NMS Plan)

• Clarify that Participants would not be obligated to pay the Historical CAT Assessment as Participants have previously paid Past CAT Costs via loans to CAT LLC, and the Historical CAT Assessment paid by Industry Members would be used by CAT LLC to repay a portion of the loans made to CAT LLC by the Participants on a pro rata basis. (Proposed Section 11.3(b)(ii) of the CAT NMS Plan)

• State that the Participants will file fee filings pursuant to Section 19(b) of the Exchange Act to charge Industry Members the Historical CAT Assessment, and such filings will provide details regarding the calculation of the Historical CAT Assessment, including the Historical Fee Rate, Historical CAT Costs, and projected volume. (Proposed Section 11.3(b)(i)(A) and (iii)(B) of the CAT NMS Plan)

II. Proposed Revisions to Proposed Amendment

CAT LLC has reviewed the SEC's OIP and the comment letter submitted in response to the OIP and it has determined to propose revisions to the Proposed Amendment. These proposed revisions are discussed in this Section II below. In addition, *Exhibit A* attached hereto sets forth the cumulative changes proposed to be made to the CAT NMS Plan, including both those changes set forth in the Proposed Amendment as well as the additional revisions proposed in Partial Amendment No. 1. *Exhibit B* attached hereto sets forth the proposed additional revisions to the Proposed Amendment as described in Partial Amendment No. 1.

A. Role of Clearing Brokers

Under the Proposed Amendment, the CBS, the CBB and the Participant would each pay a fee equal to the number of executed equivalent shares in the transaction multiplied by one-third and a specified fee rate. CAT LLC determined to assess fees upon clearing firm Industry Members because this is the current practice for other fees, such as the options regulatory fee (''ORF''), and thus this approach would reduce administrative burdens. CAT LLC acknowledged, however, that this approach may impose an excessive financial burden on clearing firms and noted that they may pass-through the CAT fees to their clients, who may pass-through their CAT fees until the fees are imposed on the account that executed the transaction. As described in the OIP, certain commenters questioned whether the Proposed Amendment would impose an undue burden on clearing firms. In response to this proposal and the related comments, the SEC requested in the OIP ''[c]ommenters' views on whether the Participants have demonstrated why imposing CAT fees only on clearing brokers, instead of on all Industry Members is consistent with the Exchange Act and Rule 608 of Regulation NMS, and whether such allocation is an unreasonable burden on competition.'' [14] In its comment letter, SIFMA raised concerns regarding the cost burden that clearing firms would experience under the Proposed Amendment.[15]

CAT LLC recognizes that imposing the fee payment obligation on clearing brokers, rather than Industry Members more generally, potentially may impose a significant financial burden on clearing firms if the fees imposed on clearing firms are not passed through to their clients. Accordingly, CAT LLC proposes to amend the Proposed Amendment to assess the payment obligation on the EBB instead of the CBB, and to assess the payment obligation on the EBS, rather than the CBS. Charging the EBBs and EBSs would reflect the executing role the EBB and EBS have in each transaction. Like with CBBs and CBSs, EBBs and EBSs also may choose to pass the CAT fee on to their clients.

To implement this change, CAT LLC proposes to state in proposed Sections 11.3(a)(iii)(A) and (b)(iii)(A) that EBBs and EBSs would have the obligation to pay the CAT Fee and the Historical CAT Assessment. Specifically, proposed Section 11.3(a)(iii)(A) would state that the EBB and EBS would be required to pay the CAT Fee:

Each Industry Member that is the executing broker for the buyer in a transaction in Eligible Securities (''Executing Broker for the Buyer'' or ''EBB'') and each Industry Member that is the executing broker for the seller in a transaction in Eligible Securities (''Executing Broker for the Seller'' or ''EBS'') will be required to pay a CAT Fee for each such transaction in Eligible Securities in the prior month based on CAT Data. The EBB's CAT Fee or EBS's CAT Fee (as applicable) for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

Similarly, proposed Section 11.3(b)(iii)(A) would state that the EBB and EBS would be required to pay the Historical CAT Assessment:

Each month in which the Historical CAT Assessment is in effect, each EBB and each EBS shall pay a fee for each transaction in Eligible Securities executed by the EBB or EBS from the prior month as set forth in CAT Data, where the Historical CAT Assessment for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Historical Fee Rate determined pursuant to paragraph (b)(i) of this Section 11.3.

B. Mid-Year Fee Adjustment

Under the Proposed Amendment, the Operating Committee may, but is not required to, adjust the Fee Rate once

[14] Request for Comment No. 8, OIP at 54578.

[15] SIFMA Letter at 4–5. CAT LLC notes, however, that, contrary to the description set forth in the SIFMA Letter, the Historical CAT Assessment would be assessed based on current market activity, not past market activity. Accordingly, the process of passing fees through for the Historical CAT Assessment would be the same as with CAT Fees related to Prospective CAT Costs.

during the year either to coordinate the CAT fees with adjustments to budgeted or actual CAT costs or actual or projected volume during the year. In response to this proposal, the SEC requested in the OIP ''[c]ommenters' views on whether the Participants should be required to change the Fee Rate when the budget or projected executed equivalent share volume changes.'' [16]

CAT LLC recognizes the need to align CAT fees with CAT costs. Requiring the adjustment of the Fee Rate mid-year in response to changes in the budgeted or actual costs or projected or actual total executed equivalent share volume during the year would likely lead to the greater alignment of CAT fees and CAT costs, thereby potentially avoiding the collection of fees in excess of CAT costs or fees that are insufficient to cover CAT costs. Accordingly, CAT LLC proposes to require a mid-year adjustment of the Fee Rate for the CAT Fee, rather than having discretion to adjust the fee mid-year. Specifically, CAT LLC proposes to state in proposed paragraph (a)(i) of Section 11.3 that ''[t]he Operating Committee will calculate the Fee Rate for the CAT Fee twice per year, once at the beginning of the year and once during the year.'' In addition, CAT LLC proposes a new paragraph (a)(i)(A)(II) of Section 11.3 that would state the following:

> During each year, the Operating Committee will calculate a new Fee Rate by dividing the budgeted CAT costs for the remainder of the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the remainder of the year. Once the Operating Committee has approved the new Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the new Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this new Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

C. Lookback Period

As described in the Proposed Amendment, the calculation of the Fee Rate requires the determination of the projected total executed equivalent share volume of transactions in Eligible Securities for the year. In the Proposed Amendment, CAT LLC proposed to determine this projection based on the total executed equivalent share volume of transactions in Eligible Securities from the prior six months. CAT LLC reasoned that the use of the data from the prior six months provides an appropriate balance between using data from a period that is sufficiently long to avoid short term fluctuations while providing data close in time to the upcoming year. In the OIP, however, the SEC asked for commenters' views on the ''use of total executed equivalent share volume from the prior six months to determine a projected total for the year instead of using the past year's total executed equivalent share volume.'' [17]

CAT LLC recognizes that the use of the prior twelve months, rather than the prior six months, would address the issue of potential seasonality. For example, the projection could be based on a period that typically has lighter trading volume than the other half of the year, thereby causing the projection to be too low. In addition, like the six-month look back, the twelve-month look back would be sufficiently long to avoid short term fluctuations in trading while providing data close in time to the upcoming year. Accordingly, CAT LLC proposes to amend the Proposed Amendment to use a twelve-month lookback for the calculation of the projection. With a twelve-month lookback, the Operating Committee would determine the projected total executed equivalent share volume of transactions in Eligible Securities for an upcoming year based on the total executed equivalent share volume from the prior twelve months. In addition, CAT LLC proposes to allow the Operating Committee to base its projection on the prior twelve months, but to use its discretion to analyze the likely volume for the upcoming year. As set forth in proposed Section 11.3(a)(iii)(B), Participants will be required to provide a description of the calculation of the projection in their fee filings pursuant to Section 19(b) of the Exchange Act.

To implement this change, CAT LLC proposes to reference the twelve-month look back period in proposed paragraphs (a)(i)(D) and (b)(i)(E) of Section 11.3 of the CAT NMS Plan. Proposed paragraph (a)(i)(D) of Section 11.3 would state that ''[t]he Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for each relevant period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.'' Similarly, proposed paragraph (b)(i)(E) of Section 11.3 of the CAT NMS Plan would state that ''[t]he Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.''

D. 19b–4 Fee Filing Process for Fee Rate Changes

The SEC has requested ''[c]ommenters' views on whether the Proposed Amendment provides sufficient clarity and detail regarding the content and process relating to the fee filing pursuant to Section 19(b) and Rule 19b–4 thereunder with regard to Fee Rate changes applicable to Industry Members.'' [18] In its comment letter, SIFMA requests that CAT LLC provide additional detail regarding the process for collecting CAT fees from Industry Members, including any triggers and/or annual review mechanisms that would result in new fee filings in the future as a result of Fee Rate changes.[19]

In response, CAT LLC proposes to restructure the proposed changes to Section 11.3 of the CAT NMS Plan, make additional changes to add clarity and detail regarding the CAT fees under the Executed Share Model, and to provide additional detail regarding the fee filing process with regard to fee rate changes applicable to Industry Members, including the requirement to calculate the Fee Rate twice per year and to make fee filings pursuant to Section 19(b) twice a year with regard to the CAT Fees for Prospective CAT Costs. Proposed Section 11.3(a) in the Proposed Amendment described the fees to be charged Participants and proposed Section 11.3(b) in the Proposed Amendment described the fees to be charged Industry Members. CAT LLC proposes to revise this structure by addressing CAT Fees related to Prospective CAT Costs in proposed Section 11.3(a) and the Historical CAT Assessment in proposed Section 11.3(b). With these changes, CAT LLC intends to make the fee filing process for setting and changing the CAT fees a straightforward and easy to implement process.

1. CAT Fees Related to Prospective CAT Costs

CAT LLC proposes to restructure and revise proposed Section 11.3(a) of the CAT NMS Plan to provide greater clarity and detail regarding CAT Fees related to Prospective CAT Costs calculated pursuant to the Executed Share Model. With the proposed additional revisions, proposed Section 11.3(a) of the CAT

[16] Request for Comment No. 9, OIP at 54578.

[17] Request for Comment No. 16, OIP at 54578.

[18] Request for Comment No. 13, OIP at 54578.

[19] SIFMA Letter at 5–7.

NMS Plan would describe that the CAT Fees related to Prospective CAT Costs apply to both Participants and Industry Members, the manner of calculating the Fee Rate, the description of the calculation of the Participant CAT Fee, a description of the calculation of the Industry Member CAT Fee, and a description of the fee filings under Section 19(b) of the Exchange Act for Industry Member CAT Fees. The following describes the proposed revisions to Section 11.3(a) of the CAT NMS Plan.

a. Introductory Statement

In the Proposed Amendment, proposed Section 11.3(a) described the fees to be charged Participants pursuant to the Executed Share Model. CAT LLC proposes to revise proposed Section 11.3(a) to address CAT Fees related to Prospective CAT Costs for both Participants and Industry Members. Accordingly, CAT LLC proposes to revise the introductory statement in proposed Section 11.3(a), which was originally proposed to state that ''[t]he Operating Committee will establish fees to be payable by Participants,'' to state that ''[t]he Operating Committee will establish fees (''CAT Fees'') to be payable by Participants and Industry Members with regard to CAT costs not previously paid by the Participants (''Prospective CAT Costs'') as follows.''

b. Calculation of the Fee Rate

CAT LLC proposes to move the description of the calculation of the Fee Rate for CAT Fees related to Prospective CAT Costs from proposed paragraph (b) of the Participant fee schedule to proposed Section 11.3(a) of the CAT NMS Plan. Moving the discussion of the calculation of the Fee Rate from the Participant fee schedule to proposed Section 11.3(a) would clarify in the CAT NMS Plan that the proposed calculation of the CAT Fee would apply to both Participants and Industry Members.

i. Fee Rate

Proposed paragraph (b)(1) of the Participant fee schedule as set forth in the Proposed Amendment describes the timing and manner of calculating the Fee Rate for CAT Fees related Prospective CAT Costs. The proposed paragraph states the following:

> The Operating Committee will calculate the Fee Rate at the beginning of each year by dividing the budgeted CAT costs for the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the year. After setting the Fee Rate at the beginning of each year, the Fee Rate may be adjusted once during the year, if necessary, due to changes in the budgeted or actual costs or projected or actual total executed equivalent share volume during the year.

CAT LLC proposes to move the description of the timing and method for calculating the Fee Rate to proposed Section 11.3(a)(i) of the CAT NMS Plan, and to provide additional detail regarding the Fee Rate in that provision. In addition, proposed Section 11.3(a)(i) will differ from the description in the Proposed Amendment as it will require the calculation of the Fee Rate twice per year, and to require the Participants to make a fee filing pursuant to Section 19(b) for Industry Member CAT Fees twice a year using the calculated Fee Rate.

Proposed Section 11.3(a)(i) of the CAT NMS Plan would state that CAT Fees related to Prospective CAT Costs will be calculated twice a year. Specifically, this proposed provision would state that ''[t]he Operating Committee will calculate the Fee Rate for the CAT Fee twice per year, once at the beginning of the year and once during the year as follows.''

Proposed Section 11.3(a)(i)(A)(I) of the CAT NMS Plan would describe the annual calculation of the Fee Rate and the requirement for Participants to file a fee filing for CAT Fees to be charged Industry Members calculated using the Fee Rate. This proposed provision also would state that Participants and Industry Members would be required to pay such CAT Fees once the CAT Fees are in effect with regard to Industry Members. This proposed provision would not change how the Fee Rate would be calculated; such calculation would be the same as described in the Proposed Amendment. Specifically, this proposed provision would state:

> At the beginning of each year, the Operating Committee will calculate the Fee Rate by dividing the budgeted CAT costs for the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the year. Once the Operating Committee has approved such Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using such Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

Proposed Section 11.3(a)(i)(A)(II) of the CAT NMS Plan describes the mid-year calculation of a new Fee Rate, as discussed above in Section II(B) of this letter. This proposed section would describe the mid-year calculation of the Fee Rate and the requirement for Participants to file a fee filing for CAT Fees to be charged Industry Members calculated using the Fee Rate. This proposed provision also would state that Participants and Industry Members would be required to pay such CAT Fees once the CAT Fees are in effect with regard to Industry Members. Specifically, this proposed provision would state:

> During each year, the Operating Committee will calculate a new Fee Rate by dividing the budgeted CAT costs for the remainder of the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the remainder of the year. Once the Operating Committee has approved the new Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the new Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this new Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

This proposed provision would not change how the Fee Rate would be calculated; such calculation would be the same as described in the Proposed Amendment. This proposed provision, however, would make the mid-year Fee Rate adjustment mandatory, rather than discretionary.

CAT LLC also proposes to add Section 11.3(a)(i)(A)(III) of the CAT NMS Plan to clarify that CAT Fees related to Prospective CAT Costs do not sunset automatically; such CAT Fees would remain in place until new CAT Fees are in place with a new Fee Rate. Specifically, this proposed provision would state:

> For the avoidance of doubt, CAT Fees with a Fee Rate calculated as set forth in this paragraph (a)(i) shall remain in effect until the Operating Committee approves a new Fee Rate as described in this paragraph (a)(i) and CAT Fees with the new Fee Rate are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

This provision clarifies, but does not change, the substance of the Proposed Amendment. This proposed change and the use of continuous fees more generally are discussed in more detail in Section II(H) of this letter.

ii. Executed Equivalent Shares

Paragraph (b)(2) of the Participant fee schedule as set forth in the Proposed Amendment describes how executed equivalent shares would be counted. CAT LLC proposes to move this proposed paragraph (b)(2) of the Participant fee schedule as set forth in the Proposed Amendment to proposed

Section 11.3(a)(i)(B) of the CAT NMS Plan. Accordingly, proposed Section 11.3(a)(i)(B) of the CAT NMS Plan would state the following:

For purposes of calculating the fees, executed equivalent shares in a transaction in Eligible Securities will be counted as follows:

(I) each executed share for a transaction in NMS Stocks will be counted as one executed equivalent share;

(II) each executed contract for a transaction in Listed Options will be counted based on the multiplier applicable to the specific Listed Option (*i.e.,* 100 executed equivalent shares or such other applicable multiplier); and

(III) each executed share for a transaction in OTC Equity Securities shall be counted as 0.01 executed equivalent share.

iii. Budgeted CAT Costs

CAT LLC proposes to move proposed paragraph (b)(3) of the Participant fee schedule as set forth in the Proposed Amendment to proposed Section 11.3(a)(i)(C). Accordingly, proposed Section 11.3(a)(i)(C) of the CAT NMS Plan would state the following, which is the same as proposed paragraph (b)(3) of the Participant fee schedule in the Proposed Amendment:

The budgeted CAT costs for the year shall be comprised of all fees, costs and expenses budgeted to be incurred by or for the Company in connection with the development, implementation and operation of the CAT as set forth in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan, or as adjusted during the year by the Operating Committee.

CAT LLC also proposes to provide additional details regarding what is included in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan in new proposed paragraphs (a)(i) and (ii) of Section 11.1 of the CAT NMS Plan. As discussed in detail below in Section II(I), proposed Section 11.1(a)(i) would describe the categories of costs to be included in the CAT budget: ''technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve, and such other cost categories as determined by the Operating Committee to be included in the budget.''

In addition, proposed Section 11.1(a)(ii) of the CAT NMS Plan would provide additional details regarding the use and size of the reserve. Specifically, proposed Section 11.1(a)(ii) of the CAT NMS Plan would state that ''[f]or the reserve referenced in paragraph (a)(i) of this Section, the budget will include an amount necessary to allow the Company to maintain a reserve of not more than 25% of the annual budget,'' and, if the CAT Fees exceed CAT costs, including the reserve, then the surplus will be used to offset future fees. An analysis of budgeted CAT costs and actual CAT costs for 2020, 2021 and the first nine months of 2022 demonstrates that actual CAT costs were approximately 20% higher than budgeted amounts over this period on a cumulative average basis. Based on the magnitude of historical budget to actual variances as well as the difficulty in accurately predicting various variable CAT costs, CAT LLC believes that a 25% reserve would appear to be reasonable. In addition, this provision would clarify that each year CAT LLC would collect sufficient funds to maintain a reserve of 25% of the annual budget. For example, if CAT LLC only had a reserve of 5% of the annual budget at the end of a year, the budget for the next year would include an additional amount for the reserve of not more than 20% of the annual budget.

iv. Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities

CAT LLC proposes to move proposed paragraph (b)(4) of the Participant fee schedule as set forth in the Proposed Amendment to proposed Section 11.3(a)(i)(D) of the CAT NMS Plan. Accordingly, proposed Section 11.3(a)(i)(D) of the CAT NMS Plan would be the same as proposed paragraph (b)(4) of the Participant fee schedule in the Proposed Amendment except for the change regarding the length of the lookback period as discussed above in Section II(C) of this letter. Specifically, Section 11.3(a)(i)(D) of the CAT NMS Plan would state that ''[t]he Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for each relevant period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.''

c. Participant CAT Fee for Prospective CAT Costs

CAT LLC proposes to describe the Participant CAT Fees related to Prospective CAT Costs in proposed Section 11.3(a)(ii) of the CAT NMS Plan. Proposed paragraph (a)(ii) of Section 11.3 would be the same as proposed Section 11.3(a)(i) and (ii) as set forth in the Proposed Amendment, with two minor changes. Instead of referring to ''a fee'' generally, the paragraph would refer to the ''CAT Fee.'' The use of the term ''CAT Fee'' would clarify that this paragraph applies to the CAT Fee related to Prospective CAT Costs, not the Historical CAT Assessment. In addition, the general reference to ''the applicable fee rate for the relevant period'' would be replaced with the more specific reference to the Fee Rate ''determined pursuant to paragraph (a)(i) of this Section 11.3.'' As discussed above, proposed Section 11.3(a)(i) describes the calculation of the Fee Rate for the CAT Fees related to Prospective CAT Costs. Accordingly, proposed Section 11.3(a)(ii)(A) of the CAT NMS Plan would state the following:

Each Participant that is a national securities exchange will be required to pay the CAT Fee for each transaction in Eligible Securities executed on the exchange in the prior month based on CAT Data. Each Participant that is a national securities association will be required to pay the CAT Fee for each transaction in Eligible Securities executed otherwise than on an exchange in the prior month based on CAT Data. The CAT Fee for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

CAT LLC also proposes to add paragraph (a)(ii)(B) to Section 11.3 of the CAT NMS Plan to clarify that Participants would only be required to pay CAT Fees when Industry Members are required to pay CAT Fees. The Executed Share Model is designed to cover 100% of CAT costs by allocating costs between and among Participants and Industry Members. However, the CAT Fees charged to Participants are implemented via a different process than CAT Fees charged to Industry Members. CAT Fees charged to Participants are implemented via an approval by the Operating Committee in accordance with the requirements of the CAT NMS Plan. In contrast, CAT Fees charged to Industry Members may only become effective in accordance with the requirements of Section 19(b) of the Exchange Act. Accordingly, proposed paragraph (a)(ii)(B) of Section 11.3 of the CAT NMS Plan would state that ''[e]ach Participant will be required to pay the CAT Fee calculated using the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3 and approved by the Operating Committee only if such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.''

d. Industry Member CAT Fees for Prospective CAT Costs

i. Industry Member CAT Fee Obligation

CAT LLC proposes to describe the CAT Fees related to Prospective CAT

Costs that are charged to Industry Members in proposed Section 11.3(a)(iii)(A) of the CAT NMS Plan. This proposed paragraph would be similar to proposed Section 11.3(b)(i) and (ii) of the CAT NMS Plan as set forth in the Proposed Amendment subject to several changes. Instead of referring to ''a fee'' generally, the paragraph would refer to the ''CAT Fee.'' The use of the term ''CAT Fee'' would clarify that this paragraph applies to the CAT Fee related to Prospective CAT Costs, not the Historical CAT Assessment. In addition, the general reference to ''the applicable fee rate for the relevant period'' would be replaced with the more specific reference to the Fee Rate ''determined pursuant to paragraph (a)(i) of this Section 11.3.'' As discussed above, proposed Section 11.3(a)(i) of the CAT NMS Plan describes the calculation of the Fee Rate for the CAT Fees related to Prospective CAT Costs. Furthermore, the proposed language would simplify the provision by eliminating repetitive language that was set forth in proposed Section 11.3(b)(i) and (ii) of the CAT NMS Plan as set forth in the Proposed Amendment. Finally, as discussed above, the provision would refer to EBBs and EBSs, rather than CBBs and CBSs. Accordingly, proposed Section 11.3(a)(iii)(A) of the CAT NMS Plan would state the following:

> Each Industry Member that is the executing broker for the buyer in a transaction in Eligible Securities (''Executing Broker for the Buyer'' or ''EBB'') and each Industry Member that is the executing broker for the seller in a transaction in Eligible Securities (''Executing Broker for the Seller'' or ''EBS'') will be required to pay a CAT Fee for each such transaction in Eligible Securities in the prior month based on CAT Data. The EBB's CAT Fee or EBS's CAT Fee (as applicable) for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

ii. Fee Filings Under Section 19(b) of the Exchange Act

CAT LLC proposes to provide additional detail as to the information that Participants would be required to include in their fee filings for CAT Fees in proposed paragraph (a)(iii)(B) of Section 11.3 of the CAT NMS Plan. The proposed paragraph sets forth the information about the CAT Fees related to Prospective CAT Costs that should be included in the fee filings required to be made by the Participants pursuant to Section 19(b) of the Exchange Act.[20] Specifically, such filings would be required to include (1) the Fee Rate; (2) the budget for the year (or remainder of the year, as applicable), including a brief description of each line item in the budget (including technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and such other categories as determined by the Operating Committee to be included in the budget) and the reason for changes in each such line item from the prior CAT Fee filing; (3) a discussion of how the budget is reconciled to the collected fees; and (4) the projected total executed equivalent share volume of all transactions in Eligible Securities for the year (or remainder of the year, as applicable), and a description of the calculation of the projection. This detail would describe how the Fee Rate is calculated, and explain how the budget used in the calculation is reconciled to the collected fees. Such detailed information would provide Industry Members and other interested parties with a clear understanding of the calculation of the CAT Fees and their relationship to CAT costs.[21]

2. Historical CAT Assessment

CAT LLC proposes to restructure and revise proposed Section 11.3(b) of the CAT NMS Plan as set forth in the Proposed Amendment to provide greater clarity and detail regarding the Historical CAT Assessment. With the proposed additional revisions, like with the description of the CAT Fee related to Prospective CAT Costs in proposed Section 11.3(a) of the CAT NMS Plan, proposed Section 11.3(b) of the CAT NMS Plan would describe the Historical CAT Assessment, including that the Historical CAT Assessment is charged to Industry Members, how it will be used to repay the Participants, the manner of calculating the Historical Fee Rate, a description of the calculation of the Historical CAT Assessment, and description of the fee filings under Section 19(b) of the Exchange Act for the Historical CAT Assessment. The following describes the proposed revisions to Section 11.3(b) of the CAT NMS Plan.

a. Introductory Statement

In the Proposed Amendment, proposed Section 11.3(b) of the CAT NMS Plan describes the fees to be charged Industry Members pursuant to the Executed Share Model. CAT LLC proposes to revise proposed Section 11.3(b) of the CAT NMS Plan to address the Historical CAT Assessment to be charged to Industry Members. Accordingly, CAT LLC proposes to revise the introductory statement in proposed Section 11.3(b) of the CAT NMS Plan, which was originally proposed to state that ''[t]he Operating Committee will establish fees to be payable by Industry Members,'' to state that ''[t]he Operating Committee will establish fees (''Historical CAT Assessment'') to be payable by Industry Members with regard to CAT costs previously paid by the Participants (''Past CAT Costs'') as follows.'' [22]

b. Calculation of Historical Fee Rate

In the Proposing Release, CAT LLC stated that Industry Member CAT fees for Past CAT Costs would be calculated in accordance with the Executed Share Model, and that the Fee Rate for the CAT fees related to Past CAT Costs would be calculated by dividing the Past CAT Costs for the relevant period (as determined by the Operating Committee) by the projected total executed equivalent share volume of all transactions in Eligible Securities for the relevant period based on CAT Data. CAT LLC proposes to provide details regarding the calculation of the Historical CAT Assessment in proposed Section 11.3(b) of the CAT NMS Plan. The detail would be similar to the detail provided in proposed Section 11.3(a) of the CAT NMS Plan regarding CAT Fees related to Prospective CAT Costs, including a description of the calculation of the Historical Fee Rate, the counting method for executed equivalent shares, the Historical CAT Costs, the Historical Recovery Period, and the projected total executed equivalent share volume of transactions in Eligible Securities for the Historical Recovery Period.

i. Historical Fee Rate

Proposed Section 11.3(b)(i)(A) of the CAT NMS Plan would describe the

[20] CAT LLC expects the fee filings required to be made by the Participants pursuant to Section 19(b) of the Exchange Act with regard to CAT Fees to be filed pursuant to Section 19(b)(3)(A) of the Exchange Act. In accordance with Section 19(b)(3)(A) of the Exchange Act, fee filings made pursuant to Section 19(b)(3)(A) of the Exchange Act would be effective upon filing.

[21] As a practical matter, the fee filing would provide the exact fee per executed equivalent share to be paid for the CAT Fees, by multiplying the Fee Rate by one-third and describing the relevant number of decimal places for the fee.

[22] Note that there may be one or more Historical CAT Assessments, depending upon the timing of any approval of the amendment to the CAT NMS Plan and the completion of the Financial Accountability Milestones. For a discussion of the Financial Accountability Milestones, *see* Section 11.6 of the CAT NMS Plan.

calculation of the Historical Fee Rate for the Historical CAT Assessment and the requirement for Participants to file a fee filing for the Historical CAT Assessment. This proposed provision also would state that Industry Members would be required to pay the Historical CAT Assessment once such Historical CAT Assessment is in effect in accordance with Section 19(b) of the Exchange Act. Specifically, this proposed provision also would state that:

> The Operating Committee will calculate the Historical Fee Rate for the Historical CAT Assessment by dividing the Historical CAT Costs by the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period. Once the Operating Committee has approved such Historical Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act the Historical CAT Assessment to be charged Industry Members calculated using such Historical Fee Rate. Industry Members will be required to pay the Historical CAT Assessment calculated using this Historical Fee Rate once such Historical CAT Assessment is in effect in accordance with Section 19(b) of the Exchange Act.

This proposed provision would not change how the Historical Fee Rate would be calculated; such calculation would be the same as described in the Proposed Amendment.

ii. Executed Equivalent Shares

As described in the Proposing Release, the Historical CAT Assessment would be calculated based on the same executed equivalent share calculation as CAT Fees related to Prospective CAT Costs. Accordingly, proposed Section 11.3(b)(i)(B) of the CAT NMS Plan would make it clear that the calculation is the same for both types of fees. Specifically, proposed Section 11.3(b)(i)(B) of the CAT NMS Plan would state that ''[f]or purposes of calculating the Historical CAT Assessment, executed equivalent shares in a transaction in Eligible Securities will be counted in the same manner as set forth in paragraph (a)(i)(B) of this Section 11.3.''

iii. Historical CAT Costs

The Proposing Release stated generally that the Operating Committee will determine the Past CAT Costs sought to be recovered through the Historical CAT Assessment. CAT LLC proposes to make this approach clear in the language of the CAT NMS Plan by adding proposed Section 11.3(b)(i)(C) of the CAT NMS Plan, which would state that ''[t]he Operating Committee will determine the Historical CAT Costs sought to be recovered by the Historical CAT Assessment, where the Historical CAT Costs will be Past CAT Costs minus Past CAT Costs excluded from Historical CAT Costs by the Operating Committee.'' As discussed below, the Historical CAT Costs, which were discussed in detail in CAT LLC's response to comments,[23] also will be discussed in the fee filings regarding the Historical CAT Assessment that are required to be made under Section 19(b) of the Exchange Act.

iv. Historical Recovery Period

The Proposing Release did not discuss the length of time during which the Historical CAT Assessment would be in effect. As the total amount of the Historical CAT Costs have not yet been determined because the fee model has not yet been approved and CAT LLC continues to incur costs, CAT LLC had not determined the appropriate recovery period. Based on CAT costs incurred to date, however, CAT LLC believes that the Historical Recovery Period should not be less than 24 months or more than five years. In analyzing the potential Historical Recovery Periods, CAT LLC sought to weigh the need for a reasonable Historical Fee Rate that spreads the Historical CAT Costs over an appropriate amount of time and the need to repay the loan notes to the Participants in a timely fashion. CAT LLC analyzed potential recovery periods using the Historical CAT Costs through 2022 as discussed in the CAT Response Letter [24] and the total executed equivalent share volume of transactions in Eligible Securities for 2021 to calculate the projected total executed equivalent share volume of transactions.[25] Based on the variables in this analysis, CAT LLC determined that the Historical Fee Rate would range from approximately $0.00002–$0.00006 per executed equivalent share for a two through five-year period. CAT LLC believes that such Historical Fee Rates would be reasonable even if Industry Members were required to pay the Historical CAT Assessment and the ongoing CAT Fee at the same time. CAT LLC notes, however, that the actual Historical CAT Assessment would be calculated using up-to-date Historical CAT Costs and executed equivalent share volume.

Proposed Section 11.3(b)(i)(D)(I) of the CAT NMS Plan would describe the Historical Recovery Period used in calculating the Historical Fee Rate. This proposed provision would state that ''[t]he length of the Historical Recovery Period used in calculating the Historical Fee Rate will be established by the Operating Committee based upon the amount of the Historical CAT Costs to be recovered by the Historical CAT Assessment.'' This proposed provision, however, would state that Historical Recovery Period used for calculating the Historical Fee Rate would not be less than 24 months or more than five years. As discussed below, the Historical Recovery Period is used to calculate the Historical Fee Rate. The actual recovery period may be longer or shorter than the Historical Recovery Period depending on the actual executed equivalent share volumes during the time that the Historical CAT Assessment is in effect.

Proposed Section 11.3(b)(i)(D)(II) of the CAT NMS Plan would describe the length of the time that the Historical CAT Assessment would be in effect, which may be greater than or less than the Historical Recovery Period, depending on the Historical CAT Assessment fees collected based on the actual volume. The Historical CAT Assessment would remain in effect until all Historical CAT Costs are collected. Accordingly, this provision states that ''[n]otwithstanding the length of the Historical Recovery Period used in calculating the Historical Fee Rate, the Historical CAT Assessment calculated using the Historical Fee Rate will remain in effect until all Historical CAT Costs are collected.''

v. Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities for Historical Recovery Period

As described in the Proposing Release, the Historical Fee Rate would be calculated by using ''the projected total executed equivalent share volume of all transactions in Eligible Securities for the relevant period based on CAT Data.'' CAT LLC proposes to clarify the manner of calculating the projected total executed equivalent share volume for the Historical CAT Assessment by adding proposed Section 11.3(b)(i)(E) to the CAT NMS Plan. CAT LLC proposes to state in this provision that the projection will be determined based on transactions in Eligible Securities for the prior twelve months. Accordingly, proposed Section 11.3(b)(i)(E) of the CAT NMS Plan would state that ''[t]he Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period based on the executed equivalent share volume of all

[23] Letter to Vanessa Countryman, Secretary, SEC, from Mike Simon, Chair, Operating Committee, CAT, (Aug. 16, 2022) at 23–28 (''CAT Response Letter'').

[24] *Id.*

[25] Proposing Release at 33246.

transactions in Eligible Securities for the prior twelve months.''

c. Past CAT Costs and Participants

As described in the Proposing Release, because the Participants have paid all CAT costs to date, the Participants would not pay the Historical CAT Assessment; only Industry Members would be required to pay the Historical CAT Assessment. Proposed Section 11.3(a)(iv) of the CAT NMS Plan as set forth in the Proposed Amendment clarified this point by stating that ''[n]otwithstanding anything to contrary, Participants will not be required to a pay a CAT fee related to CAT costs previously paid by the Participants in a manner determined by the Operating Committee ('Past CAT Costs').'' However, the Proposing Release provided additional color regarding the Participants obligations with regard to certain Past CAT Costs. Specifically, it stated that Participants would remain responsible for the one-third of Past CAT Costs allocated to Participants under the Executed Share Model, as well as 100% of certain other past CAT Costs. The CAT fees related to included Past CAT Costs would recoup two-thirds of the included Past CAT Costs; the Participants have paid for and would not be reimbursed for the remaining one-third of the included Past CAT Costs. The CAT fees related to included Past CAT Costs paid by the Industry Members would be used to reimburse the Participants for the two-thirds of included Past CAT Costs allocated to Industry Members. The CAT fees for the included Past CAT Costs collected from Industry Members will be allocated to Participants for repayment of the outstanding loan notes of the Participants to the Company on a pro rata basis; such fees would not be allocated to Participants based on the executed equivalent share volume of transactions in Eligible Securities. CAT LLC proposes to amend proposed Section 11.3 of the CAT NMS Plan to add this detail to the CAT NMS Plan.

Specifically, CAT LLC proposes to delete proposed Section 11.3(a)(iv) of the CAT NMS Plan as set forth in the Proposed Amendment and replace it with proposed Section 11.3(b)(ii) of the CAT NMS Plan. Proposed Section 11.3(b)(ii) would clarify that the Participants would not be required to pay the Historical CAT Assessment as the Participants previously have paid Past CAT Costs. It would state that, ''[b]ecause Participants previously have paid Past CAT Costs via loans to the Company, Participants would not be required to pay the Historical CAT Assessment.'' In addition, proposed Section 11.3(b)(ii) of the CAT NMS Plan would clarify that the Historical CAT fees collected from Industry Members would be allocated to Participants for repayment of the outstanding loan notes of the Participants to the Company on a pro rata basis; such fees would not be allocated to Participants based on the executed equivalent share volume of transactions in Eligible Securities. Specifically, proposed Section 11.3(b)(ii) of the CAT NMS Plan would state that ''[t]he Historical CAT Assessment to be paid by Industry Members and collected by the Company will be used by the Company to repay a portion of the loans from the Participants to the Company on a pro rata basis.'' Furthermore, proposed Section 11.3(b)(ii) of the CAT NMS Plan would emphasize that ''[t]he Historical CAT Assessment is designed to recover two-thirds of the Historical CAT Costs from Industry Members.''

d. Historical CAT Assessment for Industry Members

i. Industry Member Obligation

CAT LLC proposes to describe the Historical CAT Assessment charged to Industry Members in proposed Section 11.3(b)(iii)(A) of the CAT NMS Plan. This proposed paragraph (b)(iii)(A) of Section 11.3 of the CAT NMS Plan would be similar to proposed Section 11.3(a)(iii)(A) of the CAT NMS Plan discussed above, but would provide additional specifics regarding the Historical CAT Assessment. In particular, this paragraph would refer to the ''Historical CAT Assessment,'' ''Historical Fee Rate'' and the ''Historical Recovery Period.'' Specifically, this proposed paragraph would state that:

> Each month in which the Historical CAT Assessment is in effect, each EBB and each EBS shall pay a fee for each transaction in Eligible Securities executed by the EBB for the buyer or EBS for the seller from the prior month as set forth in CAT Data, where the Historical CAT Assessment for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Historical Fee Rate determined pursuant to paragraph (b)(i) of this Section 11.3.

ii. Fee Filings Under Section 19(b) of the Exchange Act

CAT LLC proposes to provide additional detail as to when Participants would file fee filings for the Historical CAT Assessment and what would be required to be included in such filings. Proposed Section 11.3(b)(iii)(B) would describe the requirements for filings for the Historical CAT Assessment.[26] The proposed paragraph would state that ''[w]hen the Participants file with the SEC under Section 19(b) of the Exchange Act the Historical CAT Assessment to be charged to Industry Members that the Operating Committee approved in accordance with paragraph (b) of this Section 11.3,'' the filing should set forth the following information: (1) the Historical Fee Rate; (2) a brief description of the amount and type of the Historical CAT Costs; (3) the Historical Recovery Period and the reason for its length; and (4) the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period, and a description of the calculation of the projection.[27]

E. Calculation of Past CAT Costs: Relevant Period

The SEC requested ''[c]ommenters' views on the calculation of the Past CAT Costs Fee Rate, including any views on the relevant period to be used by the Operating Committee to calculate the Fee Rate for Past CAT Costs.'' [28] As discussed above in Section II(D) of this letter, CAT LLC proposes to add substantial detail regarding the calculation of the Historical Fee Rate to proposed Section 11.3(b) of the CAT NMS Plan. Included in those proposed changes is a provision that addresses the Historical Recovery Period used in calculating the Historical Fee Rate for the Historical CAT Assessment, and a provision that addresses the length of time that the Historical CAT Assessment would be in effect.

F. Proposed Plan Changes To Describe Executed Share Model

The SEC requested ''[c]ommenters' views on the proposed changes to Section 11.3 of the CAT NMS Plan in order to conform the Plan to the Executed Shares Model by revising the manner in which fees to recover costs will be assessed on Participants and Industry Members.'' [29] As described in detail above, CAT LLC has restructured proposed Section 11.3 and added

[26] CAT LLC expects the fee filings required to be made by the Participants pursuant to Section 19(b) of the Exchange Act with regard to the Historical CAT Assessment to be filed pursuant to Section 19(b)(3)(A) of the Exchange Act. In accordance with Section 19(b)(3)(A) of the Exchange Act, fee filings made pursuant to Section 19(b)(3)(A) of the Exchange Act would be effective upon filing.

[27] As a practical matter, the fee filing would provide the exact fee per executed equivalent share to be paid for the Historical CAT Assessment, by multiplying the Historical Fee Rate by one-third and describing the relevant number of decimal places for the fee.

[28] Request for Comment No. 17, OIP at 54578.

[29] Request for Comment No. 32, OIP at 54579.

additional detail to Section 11.3 to provide a more detailed description of the implementation of the Executed Share Model in the CAT NMS Plan.

In addition, CAT LLC proposes to amend the CAT funding principles to clarify that the CAT Fee and the Historical CAT Assessment are intended to be cost-based fees—that is, the fees are designed to recover the cost of the creation, implementation and operation of the CAT. CAT LLC proposes to amend the funding principle set forth in Section 11.2(c) by making a specific reference to the costs of the CAT. With this proposed change, proposed Section 11.2(c) would state that ''[i]n establishing the funding of the Company, the Operating Committee shall seek: . . . to establish a fee structure in which the fees charged to Participants and Industry Members are based upon the executed equivalent share volume of transactions in Eligible Securities, and the costs of the CAT.''

G. Reconciliation of Budget to Fees

In the OIP, the SEC requested comment on ''whether the Proposed Amendment needs a discussion of how the budget will be reconciled to fees.'' [30] If the CAT LLC collects a surplus of fees above and beyond what is required for the CAT costs, including the requisite reserve, such surpluses would be used to offset future fees and would not be distributed to the Participants as profits.[31] To provide transparency regarding this reconciliation process, CAT LLC proposes to require that Participants provide a discussion of how the budget is reconciled to the collected fees in their fee filings pursuant Section 19(b) of the Exchange Act. CAT LLC proposes to include this requirement in Section 11.3(a)(iii)(B) of the CAT NMS Plan.

H. Continuous Fees Versus Sunsetting Fees

CAT LLC does not propose to require the proposed CAT Fees to sunset automatically; instead, a CAT Fee would continue until a new CAT Fee is in place in accordance with the requirements of the CAT NMS Plan and Section 19(b) of the Exchange Act. In response to this proposal, the SEC requested ''[c]ommenters' views on whether it is necessary or appropriate in the public interest for the Proposed Amendment to permit the Fee Rate to potentially remain in effect even if the budget or projected executed equivalent share volume changes (both would be used to calculate the Fee Rate under the Executed Share Model) or if the Fee Rate should sunset after a year. For example, if the Commission temporarily suspends and institutes proceedings to determine whether to approve or to disapprove a Section 19(b) fee filing to institute a new Fee Rate, the old Fee Rate could remain in effect during the proceedings.'' [32] In its comment letter, SIFMA advocates for a trigger or automatic review to ensure that the fee rate remains aligned with the CAT costs.[33] CAT LLC believes that the Proposed Amendment, with the revisions proposed herein, would address the concerns related to the alignment of CAT costs and CAT fees.

CAT LLC believes that it is critical that a CAT fee remain in place at all times. The financial viability of the CAT would be put at risk without a constant source of revenue. CAT LLC pays various bills, including technology bills, on a monthly basis. Accordingly, even short delays in the implementation of new CAT fees after the sunsetting of a prior CAT fee may have a deleterious effect on the operation of the CAT. Indeed, adopting sunsetting fees would contradict the funding principle of seeking to ''build financial stability to support the Company as a going concern.'' [34] CAT LLC proposes to add Section 11.3(a)(i)(A)(III) of the CAT NMS Plan to clarify that CAT Fees related to Prospective CAT Costs do not sunset automatically; such CAT Fees would remain in place until new CAT Fees with a new Fee Rate is in effect.

Moreover, CAT LLC does not believe that a sunsetting requirement is necessary to ensure that the CAT Fees are closely coordinated with Prospective CAT costs. CAT LLC has proposed a comprehensive, multi-pronged approach to ensure that the CAT Fees are closely tied to CAT costs. First, CAT LLC will be required to calculate the Fee Rates for the CAT Fees based on budgeted CAT costs. In addition, CAT LLC will be required to calculate the Fee Rate twice a year to determine whether the Fee Rate has changed due to changes in the budgeted or actual costs or actual or projected executed equivalent share volume, and to make a fee filing twice a year to reflect this calculation. Accordingly, the Fee Rate will be required to be updated twice a year, thereby ensuring the CAT Fees are closely tied to CAT costs.

Second, the CAT NMS Plan requires that the Company operate on a ''break-even'' basis, with fees imposed to cover costs and an appropriate reserve. Any surpluses would be treated as an operational reserve to offset future fees and would not be distributed to the Participants as profits. To ensure that the Participants' operation of the CAT will not contribute to the funding of their other operations, Section 11.1(c) of the CAT NMS Plan specifically states that ''[a]ny surplus of the Company's revenues over its expenses shall be treated as an operational reserve to offset future fees.'' Moreover, as discussed in detail in Section II(I) and (G) of this letter, CAT LLC proposes to amend the CAT NMS Plan to limit the reserve to no more than 25% of the annual budget and to clarify that CAT fees collected in excess of the CAT costs, including the reserve, will be used to offset future fees.[35]

Third, as discussed above in Section II(D) of this letter, CAT LLC proposes to amend the CAT NMS Plan to require Participants to provide significant details in their fee filings regarding Industry Member CAT Fees. Proposed paragraph (a)(iii)(B) of Section 11.3 of the CAT NMS Plan would state that ''[w]hen Participants file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the Fee Rate that the Operating Committee approved in accordance with paragraph (a) of this Section 11.3'' such filings would be required to include (1) the Fee Rate; (2) the budget for the upcoming year (or remainder of the year, as applicable), including a brief description of each line item in the budget (including technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and/or such other categories as determined by the Operating Committee to be included in the budget) and the reason for changes in each such line item from the prior CAT Fee filing; (3) a discussion of how the budget is reconciled to the collected fees; and (4) the projected total executed equivalent share volume of all transactions in Eligible Securities for the year (or remainder of the year, as applicable), and a description of the calculation of the projection. This detail would describe how the Fee Rate is calculated and explain how the budget used in the calculation is reconciled to the collected fees. Such detailed information would provide Industry Members and other interested parties

[30] Request for Comment No. 24, OIP at 54578.

[31] Section 11.1(c) of the CAT NMS Plan specifically states that ''[a]ny surplus of the Company's revenues over its expenses shall be treated as an operational reserve to offset future fees.''

[32] Request for Comment No. 11, OIP at 54578.

[33] SIFMA Letter at 5–7.

[34] Section 11.2(f) of the CAT NMS Plan.

[35] *See* proposed Section 11.1(a)(i) and (ii) of the CAT NMS Plan.

with a clear understanding of the calculation of the CAT fees and their relationship to CAT costs.

I. Definition of Budgeted CAT Costs

The Proposed Amendment would state that the budgeted CAT costs for the year shall be ''comprised of all fees, costs and expenses budgeted to be incurred by or for the Company in connection with the development, implementation and operation of the CAT as set forth in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan, or as adjusted during the year by the Operating Committee.'' The SEC requested ''[c]ommenters' views on the costs that would be included in the proposed definition of Budgeted CAT Costs in the Proposed Participant Fee Schedule.'' [36] CAT LLC believes that budgeted CAT costs appropriately include the costs set forth in the approved budget for CAT LLC. In addition, CAT LLC believes that using budgeted CAT costs, rather than CAT costs already incurred, allows the Company to collect fees prior to when bills become payable.

The budgeted CAT costs for the upcoming year would be the costs set forth in the annual operating budget for the Company required pursuant to Section 11.1(a) of the CAT NMS Plan. Section 11.1(a) states that ''[o]n an annual basis the Operating Committee shall approve an operating budget for the Company. The budget shall include the projected costs of the Company, including the costs of developing and operating the CAT for the upcoming year, and the sources of all revenue to cover such costs, as well as the funding of any reserve that the Operating Committee reasonably deems appropriate for prudent operation of the Company.''

The CAT costs budgeted for the year would be comprised of all fees, costs and expenses estimated to be incurred by or for the Company in connection with the development, implementation and operation of the CAT during the year. These CAT costs would include, but not be limited to, Plan Processor costs, insurance costs, third-party support costs and an operational reserve. Plan Processor costs would consist of the Plan Processor's ongoing costs, including development costs. This amount would be based upon the fees due to the Plan Processor pursuant to the Company's agreement with the Plan Processor. Insurance costs would include cyber insurance and director liability insurance. Third-party support costs would include legal fees, consulting fees, vendor fees and audit fees. In addition, the Operating Committee aims to accumulate the necessary funds to establish an operating reserve for the Company through the CAT fees charged to CAT Reporters. As set forth in Section 11.1(a) of the CAT NMS Plan, the Operating Committee may include in the budget ''funding of any reserve that the Operating Committee reasonably deems appropriate for prudent operation of the Company.'' [37] CAT LLC proposes to add proposed Section 11.1(a)(i) to provide additional clarity regarding the costs to be included in the CAT budget by listing the types of CAT costs to be included in the budget. Specifically, proposed Section 11.1(a)(i) of the CAT NMS Plan would state that ''[w]ithout limiting the foregoing, the budgeted CAT costs shall include technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve, and such other categories as determined by the Operating Committee to be included in the budget.''

As required by Section 11.1(c) of the CAT NMS Plan, any surpluses collected will be treated as an operational reserve to offset future fees and will not be distributed to the Participants as profits. In the Proposed Amendment, CAT LLC stated that ''[a]lthough the Operating Committee may determine at its discretion that a different level of reserves is appropriate in the future, the Operating Committee proposes to include in the budget for purposes of determining CAT fees an operational reserve comprised of three months of ongoing CAT costs.'' [38] To provide additional clarity regarding the size of the reserve, CAT LLC proposes to add proposed paragraph (a)(ii) to Section 11.1 of the CAT NMS Plan to set forth the parameters for the size of the reserve. Specifically, proposed Section 11.1(a)(ii) of the CAT NMS Plan would state that ''[t]he budget will include a reserve in the amount of not more than 25% of the annual budget.'' In addition, CAT LLC proposes to clarify how CAT fees collected in excess of CAT costs, including the reserve, would be used. Specifically, proposed paragraph (a)(ii) of Section 11.1 of the CAT NMS Plan would state that ''[t]o the extent collected CAT fees exceed CAT costs, including the reserve of 25% of the annual budget, such surplus will be used to offset future fees.''

To address potential changes related to the CAT during the year, the Operating Committee may adjust the budgeted CAT costs for the year as it reasonably deems appropriate for the prudent operation of the Company. For example, the Operating Committee may determine that an adjustment to the budget is necessary if actual costs during the year are more or less than the budget, or if unanticipated expenditures are necessary. To the extent that the Operating Committee adjusts the budgeted CAT costs during the year and determines to adjust the Fee Rate, the adjusted budgeted CAT costs would be used in calculating the new Fee Rate for the remaining months of the year.

The Operating Committee has determined to publicly provide the annual operating budget for the Company as well as any updates to the budget that occur during the year. This publicly available budget information describes in detail the budget for the Company. For example, among other things, the budget provides specific budgeted technology costs (including cloud hosting services, operating fees, Customer and Account Information System (''CAIS'') operating fees and change request fees) and general and administrative costs (including legal, consulting, insurance, professional and administration, and public relations). The Company provides such budget information on a dedicated web page on the CAT NMS Plan website to make it readily accessible for CAT Reporters and others.

III. Solicitation of Comments

The Commission seeks comments on the Proposed Amendment, as modified by Partial Amendment No. 1. Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the Proposed Amendment, as modified by Partial Amendment No. 1 is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number 4–698 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 4–698. This file number should be included on the subject line if email is used. To help the Commission

[36] Request for Comment No. 24, OIP at 54578.

[37] Section 11.1(a) of the CAT NMS Plan.

[38] Proposing Release at 33228.

process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to Partial Amendment No. 1 that are filed with the Commission, and all written communications relating to Partial Amendment No. 1 between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the Participants' offices. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–698 and should be submitted on or before December 23, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

Sherry R. Haywood,

Assistant Secretary.

EXHIBIT A:

Cumulative Proposed Revisions to CAT NMS Plan

Additions *italicized;* deletions [bracketed]

* * * * *

ARTICLE I

DEFINITIONS

* * * * *

[''Execution Venue'' means a Participant or an alternative trading system (''ATS'') (as defined in Rule 300 of Regulation ATS) that operates pursuant to Rule 301 of Regulation ATS (excluding any such ATS that does not execute orders).]

* * * * *

ARTICLE XI

FUNDING OF THE COMPANY

Section 11.1. Funding Authority.

(a) On an annual basis the Operating Committee shall approve an operating budget for the Company. The budget shall include the projected costs of the Company, including the costs of developing and operating the CAT for the upcoming year, and the sources of all revenues to cover such costs, as well as the funding of any reserve that the Operating Committee reasonably deems appropriate for prudent operation of the Company.

(i) Without limiting the foregoing, the budgeted CAT costs shall include technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and such other cost categories as determined by the Operating Committee to be included in the budget.

(ii) For the reserve referenced in paragraph (a)(i) of this Section, the budget will include an amount necessary to allow the Company to maintain a reserve of not more than 25% of the annual budget. To the extent collected CAT fees exceed CAT costs, including the reserve of 25% of the annual budget, such surplus shall be used to offset future fees.

(b) Subject to Section 11.2, the Operating Committee shall have discretion to establish funding for the Company, including: (i) establishing fees that the Participants shall pay; and (ii) establishing fees for Industry Members that shall be implemented by Participants. The Participants shall file with the SEC under Section 19(b) of the Exchange Act any such fees on Industry Members that the Operating Committee approves, and such fees shall be labeled as ''Consolidated Audit Trail Funding Fees.''

(c) To fund the development and implementation of the CAT, the Company shall time the imposition and collection of all fees on Participants and Industry Members in a manner reasonably related to the timing when the Company expects to incur such development and implementation costs. In determining fees on Participants and Industry Members the Operating Committee shall take into account fees, costs and expenses (including legal and consulting fees and expenses) incurred by the Participants on behalf of the Company prior to the Effective Date in connection with the creation and implementation of the CAT, and such fees, costs and expenses shall be fairly and reasonably shared among the Participants and Industry Members. Any surplus of the Company's revenues over its expenses shall be treated as an operational reserve to offset future fees.

(d) Consistent with this Article XI, the Operating Committee shall adopt policies, procedures, and practices regarding the budget and budgeting process, [assignment of tiers,] resolution of disputes, billing and collection of fees, and other related matters. [For the avoidance of doubt, as part of its regular review of fees for the CAT, the Operating Committee shall have the right to change the tier assigned to any particular Person in accordance with fee schedules previously filed with the Commission that are reasonable, equitable and not unfairly discriminatory and subject to public notice and comment, pursuant to this Article XI. Any such changes will be effective upon reasonable notice to such Person.]

Section 11.2. Funding Principles. In establishing the funding of the Company, the Operating Committee shall seek:

(a) to create transparent, predictable revenue streams for the Company that are aligned with the anticipated costs to build, operate and administer the CAT and the other costs of the Company;

(b) to establish an allocation of the Company's related costs among Participants and Industry Members that is consistent with the Exchange Act, taking into account the timeline for implementation of the CAT [and distinctions in the securities trading operations of Participants and Industry Members and their relative impact upon Company resources and operations];

(c) to establish a [tiered] fee structure in which the fees charged to [: (i)] *Participants and* [CAT Reporters that are Execution Venues, including ATSs, are based upon the level of market share; (ii)] Industry Members[' non-ATS activities] are based upon *the executed equivalent share volume of transactions in Eligible Securities, and the costs of the CAT* [message traffic; and (iii) the CAT Reporters with the most CAT-related activity (measured by market share and/or message traffic, as applicable) are generally comparable (where, for these comparability purposes, the tiered fee structure takes into consideration affiliations between or among CAT Reporters, whether Execution Venues and/or Industry Members)].

(d) to provide for ease of billing and other administrative functions;

(e) to avoid any disincentives such as placing an inappropriate burden on competition and a reduction in market quality; and

(f) to build financial stability to support the Company as a going concern.

Section 11.3. Recovery.

(a) The Operating Committee will establish [fixed] fees *(''CAT Fees'')* to be payable by [Execution Venues] *Participants and Industry Members with*

[39] 17 CFR 200.30–3(a)(12).

regard to CAT costs not previously paid by the Participants (''Prospective CAT Costs'') as follows [provided in this Section 11.3(a)]:

(i) *Fee Rate. The Operating Committee will calculate the Fee Rate for the CAT Fee twice per year, once at the beginning of the year and once during the year.*

(A) General.

(I) *At the beginning of each year, the Operating Committee will calculate the Fee Rate by dividing the budgeted CAT costs for the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the year. Once the Operating Committee has approved such Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using such Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(II) *During each year, the Operating Committee will calculate a new Fee Rate by dividing the budgeted CAT costs for the remainder of the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the remainder of the year. Once the Operating Committee has approved the new Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the new Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this new Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(III) *For the avoidance of doubt, CAT Fees with a Fee Rate calculated as set forth in this paragraph (a)(i) shall remain in effect until the Operating Committee approves a new Fee Rate as described in paragraph (a)(i) and CAT Fees with the new Fee Rate are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(B) Executed Equivalent Shares. For purposes of calculating CAT Fees, executed equivalent shares in a transaction in Eligible Securities will be counted as follows:

(I) each executed share for a transaction in NMS Stocks will be counted as one executed equivalent share;

(II) each executed contract for a transaction in Listed Options will be counted based on the multiplier applicable to the specific Listed Option (i.e., 100 executed equivalent shares or such other applicable multiplier); and

(III) each executed share for a transaction in OTC Equity Securities shall be counted as 0.01 executed equivalent share.

(C) Budgeted CAT Costs. The budgeted CAT costs for the year shall be comprised of all fees, costs and expenses budgeted to be incurred by or for the Company in connection with the development, implementation and operation of the CAT as set forth in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan, or as adjusted during the year by the Operating Committee.

(D) Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities. The Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for each relevant period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.

(ii) Participant CAT Fees.

(A) CAT Fee Obligation. Each Participant that is a national securities exchange will be required to pay the CAT Fee for each transaction in Eligible Securities executed on the exchange in the prior month based on CAT Data. Each Participant that is a national securities association will be required to pay the CAT Fee for each transaction in Eligible Securities executed otherwise than on an exchange in the prior month based on CAT Data. The CAT Fee for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

(B) Effectiveness. Each Participant will be required to pay the CAT Fee calculated using the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3 and approved by the Operating Committee only if such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

(iii) Industry Member CAT Fees.

(A) CAT Fee Obligation. Each Industry Member that is the executing broker for the buyer in a transaction in Eligible Securities (''Executing Broker for the Buyer'' or ''EBB'') and each Industry Member that is the executing broker for the seller in a transaction in Eligible Securities (''Executing Broker for the Seller'' or ''EBS'') will be required to pay a CAT Fee for each such transaction in Eligible Securities in the prior month based on CAT Data. The EBB's CAT Fee or EBS's CAT Fee (as applicable) for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

(B) Content of Fee Filings. When Participants file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the Fee Rate that the Operating Committee approved in accordance with paragraph (a) of this Section 11.3, such filings shall set forth (A) the Fee Rate; (B) the budget for the upcoming year (or remainder of the year, as applicable), including a brief description of each line item in the budget, including technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and/or such other categories as determined by the Operating Committee to be included in the budget, and the reason for changes in each such line item from the prior CAT Fee filing; (C) a discussion of how the budget is reconciled to the collected fees; and (D) the projected total executed equivalent share volume of all transactions in Eligible Securities for the year (or remainder of the year, as applicable), and a description of the calculation of the projection.

[(i) Each Execution Venue that: (A) executes transactions; or (B) in the case of a national securities association, has trades reported by its members to its trade reporting facility or facilities for reporting transactions effected otherwise than on an exchange, in NMS Stocks or OTC Equity Securities will pay a fixed fee depending on the market share of that Execution Venue in NMS Stocks and OTC Equity Securities, with the Operating Committee establishing at least two and no more than five tiers of fixed fees, based on an Execution Venue's NMS Stocks and OTC Equity Securities market share. For these purposes, market share for Execution Venues that execute transactions will be calculated by share volume, and market share for a national securities association that has trades reported by its members to its trade reporting facility or facilities for reporting transactions effected otherwise than on an exchange in NMS Stocks or OTC Equity Securities will be calculated based on share volume of trades reported, provided, however, that the share volume reported to such national securities association by an Execution

Venue shall not be included in the calculation of such national security association's market share.]

[(ii) Each Execution Venue that executes transactions in Listed Options will pay a fixed fee depending on the Listed Options market share of that Execution Venue, with the Operating Committee establishing at least two and no more than five tiers of fixed fees, based on an Execution Venue's Listed Options market share. For these purposes, market share will be calculated by contract volume.]

(b) *Past CAT Costs.* The Operating Committee will establish [fixed] fees *(''Historical CAT Assessment'')* to be payable by Industry Members *with regard to CAT costs previously paid by the Participants (''Past CAT Costs'') as follows:* [, based on the message traffic generated by such Industry Member, with the Operating Committee establishing at least five and no more than nine tiers of fixed fees, based on message traffic. For the avoidance of doubt, the fixed fees payable by Industry Members pursuant to this paragraph shall, in addition to any other applicable message traffic, include message traffic generated by: (i) an ATS that does not execute orders that is sponsored by such Industry Member; and (ii) routing orders to and from any ATS sponsored by such Industry Member.]

(i) *Calculation of Historical Fee Rate.*

(A) General. The Operating Committee will calculate the Historical Fee Rate for the Historical CAT Assessment by dividing the Historical CAT Costs by the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period. Once the Operating Committee has approved such Historical Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act the Historical CAT Assessment to be charged Industry Members calculated using such Historical Fee Rate. Industry Members will be required to pay the Historical CAT Assessment calculated using this Historical Fee Rate once such Historical CAT Assessment is in effect in accordance with Section 19(b) of the Exchange Act.

(B) Executed Equivalent Shares. For purposes of calculating the Historical CAT Assessment, executed equivalent shares in a transaction in Eligible Securities will be counted in the same manner as set forth in paragraph (a)(i)(B) of this Section 11.3.

(C) Historical CAT Costs. The Operating Committee will determine the Historical CAT Costs sought to be recovered by the Historical CAT Assessment, where the Historical CAT Costs will be Past CAT Costs minus Past CAT Costs excluded from Historical CAT Costs by the Operating Committee.

(D) Historical Recovery Period.

(I) *The length of the Historical Recovery Period used in calculating the Historical Fee Rate will be established by the Operating Committee based upon the amount of the Historical CAT Costs to be recovered by the Historical CAT Assessment; provided, however, no Historical Recovery Period used in calculating the Historical Fee Rate shall be less than 24 months or more than five years.*

(II) *Notwithstanding the length of the Historical Recovery Period used in calculating the Historical Fee Rate, the Historical CAT Assessment calculated using the Historical Fee Rate will remain in effect until all Historical CAT Costs are collected.*

(E) Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities for Historical Recovery Period. The Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.

(ii) Past CAT Costs and Participants. Because Participants previously have paid Past CAT Costs via loans to the Company, Participants would not be required to pay the Historical CAT Assessment. The Historical CAT Assessment to be paid by Industry Members and collected by the Company will be used by the Company to repay a portion of the loans from the Participants to the Company on a pro rata basis. The Historical CAT Assessment is designed to recover two-thirds of the Historical CAT Costs.

(iii) *Historical CAT Assessment for Industry Members.*

(A) Each month in which the Historical CAT Assessment is in effect, each EBB and each EBS shall pay a fee for each transaction in Eligible Securities executed by the EBB or EBS from the prior month as set forth in CAT Data, where the Historical CAT Assessment for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Historical Fee Rate determined pursuant to paragraph (b)(i) of this Section 11.3.

(B) Historical CAT Fee Filing. When the Participants file with the SEC pursuant to Section 19(b) of the Exchange Act the Historical CAT Assessment calculated using the Historical Fee Rate that the Operating Committee approved in accordance with this Section 11.3, such filing shall set forth (A) the Historical Fee Rate; (B) a brief description of amount and type of the Historical CAT Costs; (C) the Historical Recovery Period and the reasons for its length; and (D) the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period, and a description of the calculation of the projection.

(c) The Operating Committee may establish any other fees ancillary to the operation of the CAT that it reasonably determines appropriate, including fees: (i) for the late or inaccurate reporting of information to the CAT; (ii) for correcting submitted information; and (iii) based on access and use of the CAT for regulatory and oversight purposes (and not including any reporting obligations).

(d) The Company shall make publicly available a schedule of effective fees and charges adopted pursuant to this Agreement as in effect from time to time. The Operating Committee shall review such fee schedule on at least an annual basis and shall make any changes to such fee schedule that it deems appropriate. The Operating Committee is authorized to review such fee schedule on a more regular basis, but shall not make any changes on more than a semiannual basis unless, pursuant to a Supermajority Vote, the Operating Committee concludes that such change is necessary for the adequate funding of the Company.

* * * * *

APPENDIX B

Fee Schedule

Consolidated Audit Trail Funding Fees for Participants

(a) CAT Fee. Each Participant shall pay the CAT Fee set forth in Section 11.3(a) of the CAT NMS Plan to Consolidated Audit Trail, LLC in the manner prescribed by Consolidated Audit Trail, LLC on a monthly basis based on the Participant's transactions in Eligible Securities in the prior month.

* * * * *

EXHIBIT B:

Proposed Additional Revisions to Proposed Changes in Proposed Amendment

Additions *italicized;* deletions [bracketed]

* * * * *

ARTICLE XI

FUNDING OF THE COMPANY

Section 11.1. Funding Authority.

(a) On an annual basis the Operating Committee shall approve an operating budget for the Company. The budget shall include the projected costs of the Company, including the costs of developing and operating the CAT for the upcoming year, and the sources of all revenues to cover such costs, as well as the funding of any reserve that the Operating Committee reasonably deems appropriate for prudent operation of the Company.

(i) Without limiting the foregoing, the budgeted CAT costs shall include technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and such other cost categories as determined by the Operating Committee to be included in the budget.

(ii) For the reserve referenced in paragraph (a)(i) of this Section, the budget will include an amount necessary to allow the Company to maintain a reserve of not more than 25% of the annual budget. To the extent collected CAT fees exceed CAT costs, including the reserve of 25% of the annual budget, such surplus shall be used to offset future fees.

(b) Subject to Section 11.2, the Operating Committee shall have discretion to establish funding for the Company, including: (i) establishing fees that the Participants shall pay; and (ii) establishing fees for Industry Members that shall be implemented by Participants. The Participants shall file with the SEC under Section 19(b) of the Exchange Act any such fees on Industry Members that the Operating Committee approves, and such fees shall be labeled as ''Consolidated Audit Trail Funding Fees.''

(c) To fund the development and implementation of the CAT, the Company shall time the imposition and collection of all fees on Participants and Industry Members in a manner reasonably related to the timing when the Company expects to incur such development and implementation costs. In determining fees on Participants and Industry Members the Operating Committee shall take into account fees, costs and expenses (including legal and consulting fees and expenses) incurred by the Participants on behalf of the Company prior to the Effective Date in connection with the creation and implementation of the CAT, and such fees, costs and expenses shall be fairly and reasonably shared among the Participants and Industry Members. Any surplus of the Company's revenues over its expenses shall be treated as an operational reserve to offset future fees.

(d) Consistent with this Article XI, the Operating Committee shall adopt policies, procedures, and practices regarding the budget and budgeting process, resolution of disputes, billing and collection of fees, and other related matters.

Section 11.2. Funding Principles. In establishing the funding of the Company, the Operating Committee shall seek:

(a) to create transparent, predictable revenue streams for the Company that are aligned with the anticipated costs to build, operate and administer the CAT and the other costs of the Company;

(b) to establish an allocation of the Company's related costs among Participants and Industry Members that is consistent with the Exchange Act, taking into account the timeline for implementation of the CAT;

(c) to establish a fee structure in which the fees charged to Participants and Industry Members are based upon the executed equivalent share volume of transactions in Eligible Securities*, and the costs of the CAT.*

(d) to provide for ease of billing and other administrative functions;

(e) to avoid any disincentives such as placing an inappropriate burden on competition and a reduction in market quality; and

(f) to build financial stability to support the Company as a going concern.

Section 11.3. Recovery.

(a) *Prospective CAT Costs.* The Operating Committee will establish fees *(''CAT Fees'')* to be payable by Participants *and Industry Members with regard to CAT costs not previously paid by the Participants (''Prospective CAT Costs'')* as follows:

(i) *Fee Rate. The Operating Committee will calculate the Fee Rate for the CAT Fee twice per year, once at the beginning of the year and once during the year as follows:*

(A) General.

(I) *At the beginning of each year, the Operating Committee will calculate the Fee Rate by dividing the budgeted CAT costs for the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the year. Once the Operating Committee has approved such Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using such Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(II) *During each year, the Operating Committee will calculate a new Fee Rate by dividing the budgeted CAT costs for the remainder of the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the remainder of the year. Once the Operating Committee has approved the new Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the new Fee Rate. Participants and Industry Members will be required to pay CAT Fees calculated using this new Fee Rate once such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(III) *For the avoidance of doubt, CAT Fees with a Fee Rate calculated as set forth in this paragraph (a)(i) shall remain in effect until the Operating Committee approves a new Fee Rate as described in paragraph (a)(i) and CAT Fees with the new Fee Rate are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.*

(B) Executed Equivalent Shares. For purposes of calculating CAT Fees, executed equivalent shares in a transaction in Eligible Securities will be counted as follows:

(I) each executed share for a transaction in NMS Stocks will be counted as one executed equivalent share;

(II) each executed contract for a transaction in Listed Options will be counted based on the multiplier applicable to the specific Listed Option (*i.e.,* 100 executed equivalent shares or such other applicable multiplier); and

(III) each executed share for a transaction in OTC Equity Securities shall be counted as 0.01 executed equivalent share.

(C) Budgeted CAT Costs. The budgeted CAT costs for the year shall be comprised of all fees, costs and expenses budgeted to be incurred by or for the Company in connection with the development, implementation and operation of the CAT as set forth in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan, or as adjusted during the year by the Operating Committee.

(D) Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities. The Operating Committee shall determine the projected total executed equivalent

share volume of all transactions in Eligible Securities for each relevant period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.

(ii) Participant CAT Fees.

(A) CAT Fee Obligation. Each Participant that is a national securities exchange will be required to pay [a fee] *the CAT Fee* for each transaction in Eligible Securities executed on the exchange in the prior month based on CAT Data. Each Participant that is a national securities association will be required to pay [a fee] *the CAT Fee* for each transaction in Eligible Securities executed otherwise than on an exchange in the prior month based on CAT Data. [(ii)] The [fee] *CAT Fee* for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the [applicable fee rate for the relevant period (''] Fee Rate ['')] *determined pursuant to paragraph (a)(i) of this Section 11.3.*

(B) Effectiveness. Each Participant will be required to pay the CAT Fee calculated using the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3 and approved by the Operating Committee only if such CAT Fees are in effect with regard to Industry Members in accordance with Section 19(b) of the Exchange Act.

[(iii) Participants will be required to pay a CAT fee with regard to CAT costs not previously paid by the Participants (''Prospective CAT Costs''). The Fee Rate for the CAT fee related to Prospective CAT Costs will be calculated by dividing the budgeted CAT costs for the relevant period (as determined by the Operating Committee) by the projected total executed equivalent share volume of all transactions in Eligible Securities for the relevant period based on CAT Data.]

[(iv) Notwithstanding anything to the contrary, Participants will not be required to pay a CAT fee related to CAT costs previously paid by the Participants in a manner determined by the Operating Committee (''Past CAT Costs'').]

(iii) Industry Member CAT Fees.

(A) CAT Fee Obligation. Each Industry Member that is the executing broker for the buyer in a transaction in Eligible Securities (''Executing Broker for the Buyer'' or ''EBB'') and each Industry Member that is the executing broker for the seller in a transaction in Eligible Securities (''Executing Broker for the Seller'' or ''EBS'') will be required to pay a CAT Fee for each such transaction in Eligible Securities in the prior month based on CAT Data. The EBB's CAT Fee or EBS's CAT Fee (as applicable) for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate determined pursuant to paragraph (a)(i) of this Section 11.3.

(B) Content of Fee Filings. When the Participants file with the SEC pursuant to Section 19(b) of the Exchange Act CAT Fees to be charged to Industry Members calculated using the Fee Rate that the Operating Committee approved in accordance with paragraph (a) of this Section 11.3, such filings shall set forth (A) the Fee Rate; (B) the budget for the upcoming year (or remainder of the year, as applicable), including a brief description of each line item in the budget, including technology, legal, consulting, insurance, professional and administration, and public relations costs, a reserve and/or such other categories as determined by the Operating Committee to be included in the budget, and the reason for changes in each such line item from the prior CAT Fee filing; (C) a discussion of how the budget is reconciled to the collected fees; and (D) the projected total executed equivalent share volume of all transactions in Eligible Securities for the year (or remainder of the year, as applicable), and a description of the calculation of the projection.

(b) *Past CAT Costs.* The Operating Committee will establish fees (''Historical CAT Assessment'') to be payable by Industry Members *with regard to CAT costs previously paid by the Participants (''Past CAT Costs'')* as follows:

(i) Calculation of Historical Fee Rate.

(A) General. The Operating Committee will calculate the Historical Fee Rate for the Historical CAT Assessment by dividing the Historical CAT Costs by the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period. Once the Operating Committee has approved such Fee Rate, the Participants shall be required to file with the SEC pursuant to Section 19(b) of the Exchange Act the Historical CAT Assessment to be charged to Industry Members calculated using such Historical Fee Rate. Industry Members will be required to pay Historical CAT Assessment calculated using this Historical Fee Rate once such Historical CAT Assessment is in effect in accordance with Section 19(b) of the Exchange Act.

(B) Executed Equivalent Shares. For purposes of calculating the Historical CAT Assessment, executed equivalent shares in a transaction in Eligible Securities will be counted in the same manner as set forth in paragraph (a)(i)(B) of this Section 11.3.

(C) Historical CAT Costs. The Operating Committee will determine the Historical CAT Costs sought to be recovered by the Historical CAT Assessment, where the Historical CAT Costs will be Past CAT Costs minus Past CAT Costs excluded from Historical CAT Costs by the Operating Committee.

(D) Historical Recovery Period.

(I) *The length of the Historical Recovery Period used in calculating the Historical Fee Rate will be established by the Operating Committee based upon the amount of the Historical CAT Costs to be recovered by the Historical CAT Assessment; provided, however, no Historical Recovery Period used in calculating the Historical Fee Rate shall be less than 24 months or more than five years.*

(II) *Notwithstanding the length of the Historical Recovery Period used in calculating the Historical Fee Rate, the Historical CAT Assessment calculated using the Historical Fee Rate will remain in effect until all Historical CAT Costs are collected.*

(E) Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities for Historical Recovery Period. The Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior twelve months.

(ii) Past CAT Costs and Participants. Because Participants previously have paid Past CAT Costs via loans to the Company, Participants would not be required to pay the Historical CAT Assessment. The Historical CAT Assessment to be paid by Industry Members and collected by the Company will be used by the Company to repay a portion of the loans from the Participants to the Company on a pro rata basis. The Historical CAT Assessment is designed to recover two-thirds of the Historical CAT Costs.

(iii) *Historical CAT Assessment for Industry Members.*

(A) Each month in which the Historical CAT Assessment is in effect, each EBB and each EBs shall pay a fee for each transaction in Eligible Securities executed by the EBB or EBS from the prior month as set forth in CAT Data, where the Historical CAT Assessment for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the

Historical Fee Rate determined pursuant to paragraph (b)(i) of this Section 11.3.

(B) Historical CAT Fee Filing. When the Participants file with the SEC pursuant to Section 19(b) of the Exchange Act the Historical CAT Assessment calculated using the Historical Fee Rate that the Operating Committee approved in accordance with paragraph (b) of this Section 11.3, such filing shall set forth (A) the Historical Fee Rate; (B) a brief description of the amount and type of the Historical CAT Costs; (C) the Historical Recovery Period and the reasons for its length; and (D) the projected total executed equivalent share volume of all transactions in Eligible Securities for the Historical Recovery Period, and a description of the calculation of the projection.

[(i) Each Industry Member that is the clearing firm for the buyer in a transaction in Eligible Securities (''Clearing Broker for the Buyer'' or ''CBB'') will be required to pay a fee for each such transaction in Eligible Securities based on CAT Data. The CBB's fee for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate.]

[(ii) Each Industry Member that is the clearing firm for the seller in a transaction in Eligible Securities (''Clearing Broker for the Seller'' or ''CBS'') will be required to pay a fee for each transaction in Eligible Securities based on CAT Data. The CBS's fee for each transaction in Eligible Securities will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate.]

[(iii) CBBs and CBSs will be required to pay CAT fees related to Past CAT Costs. The Fee Rate for the CAT fees related to Past CAT Costs will be calculated by dividing the Past CAT Costs for the relevant period (as determined by the Operating Committee) by the projected total executed equivalent share volume of all transactions in Eligible Securities for the relevant period based on CAT Data.]

[(iv) CBBs and CBSs will be required to pay CAT fees related to Prospective CAT Costs. The Fee Rate for the CAT fees related to Prospective CAT Costs will be the same as set forth in paragraph (a)(iv) above.]

(c) The Operating Committee may establish any other fees ancillary to the operation of the CAT that it reasonably determines appropriate, including fees: (i) for the late or inaccurate reporting of information to the CAT; (ii) for correcting submitted information; and (iii) based on access and use of the CAT for regulatory and oversight purposes (and not including any reporting obligations).

(d) The Company shall make publicly available a schedule of effective fees and charges adopted pursuant to this Agreement as in effect from time to time. The Operating Committee shall review such fee schedule on at least an annual basis and shall make any changes to such fee schedule that it deems appropriate. The Operating Committee is authorized to review such fee schedule on a more regular basis, but shall not make any changes on more than a semiannual basis unless, pursuant to a Supermajority Vote, the Operating Committee concludes that such change is necessary for the adequate funding of the Company.

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APPENDIX B

Fee Schedule

Consolidated Audit Trail Funding Fees for Participants

(a) CAT Fee.

[(1) Each Participant that is a national securities exchange shall pay a fee for each transaction in Eligible Securities executed on the exchange based on CAT Data, where the fee for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate.

(2) Each Participant that is a national securities association shall pay a fee for each transaction in Eligible Securities executed otherwise than on exchange based on CAT Data, where the fee for each transaction will be calculated by multiplying the number of executed equivalent shares in the transaction by one-third and by the Fee Rate.

(b) Fee Rate.

(1) The Operating Committee will calculate the Fee Rate at the beginning of each year by dividing the budgeted CAT costs for the year by the projected total executed equivalent share volume of all transactions in Eligible Securities for the year. After setting the Fee Rate at the beginning of each year, the Fee Rate may be adjusted once during the year, if necessary, due to changes in the budgeted or actual costs or projected or actual total executed equivalent share volume during the year.

(2) For purposes of calculating the fees, executed equivalent shares in a transaction in Eligible Securities will be counted as follows:

(i) each executed share for a transaction in NMS Stocks will be counted as one executed equivalent share;

(ii) each executed contract for a transaction in Listed Options will be counted based on the multiplier applicable to the specific Listed Option (*i.e.,* 100 executed equivalent shares or such other applicable multiplier); and

(iii) each executed share for a transaction in OTC Equity Securities shall be counted as 0.01 executed equivalent share.

(3) Budgeted CAT Costs. The budgeted CAT costs for the year shall be comprised of all fees, costs and expenses budgeted to be incurred by or for the Company in connection with the development, implementation and operation of the CAT as set forth in the annual operating budget approved by the Operating Committee pursuant to Section 11.1(a) of the CAT NMS Plan, or as adjusted during the year by the Operating Committee.

(4) Projected Total Executed Equivalent Share Volume of Transactions in Eligible Securities. The Operating Committee shall determine the projected total executed equivalent share volume of all transactions in Eligible Securities for each relevant period based on the executed equivalent share volume of all transactions in Eligible Securities for the prior six months.]

[(c) Fee Payments/Collection.] Each Participant shall pay the CAT *Fee* [fee] set forth *in Section 11.3(a) of the CAT NMS Plan* [paragraph (a)] to Consolidated Audit Trail, LLC in the manner prescribed by Consolidated Audit Trail, LLC on a monthly basis based on the Participant's transactions *in Eligible Securities* in the prior month.

* * * * *

[FR Doc. 2022–26235 Filed 12–1–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96395; File No. SR–CBOE–2022–058]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Amend Rule 10.3 Regarding Margin Requirements

November 28, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend Rule 10.3 regarding margin requirements. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 10.3 Margin Requirements

(a)–(b) No change.

(c) *Customer Margin Account—Exception.* The foregoing requirements are subject to the following exceptions. Nothing in this paragraph (c) shall prevent a broker-dealer from requiring margin from any account in excess of the amounts specified in these provisions.

(1)–(4) No change.

(5) *Initial and Maintenance Margin Requirements on Short Options, Stock Index Warrants, Currency Index Warrants and Currency Warrants.*

(A)–(B) No change.

(C) *Related Securities Positions—Listed or OTC Options.* Unless otherwise specified, margin must be deposited and maintained in the following amounts for each of the following types of positions.

(i)–(ii) No change.

(iii) *Covered Calls/Covered Puts.* [(a)] No margin is required for a call (put) option contract or warrant carried in a short position where there is carried in the same account a long (short) position in equivalent units of the underlying security.

[(b) No margin is required for a call (put) index option contract or warrant carried in a short position where there is carried in the same account a long (short) position in an (1) underlying stock basket, (2) index mutual fund, (3) IPR, or (4) IPS, that is based on the same index underlying the index option or warrant and having a market value at least equal to the aggregate current index value.

(c)] In order for th[e]*is* exception[s in subparagraphs (a) and (b) above] to apply, in computing margin on positions in the underlying security[, underlying stock basket, index mutual fund, IPR or IPS, as applicable], ([1]*a*) in the case of a call, the current market value to be used shall not be greater than the exercise price, and ([2]*b*) in the case of a put, margin shall be the amount required by subparagraph (b)(2) of this Rule, plus the amount, if any, by which the exercise price exceeds the current market value.

(iv) *Exceptions.* The following paragraphs set forth the minimum amount of margin which must be maintained in margin accounts of customers having positions in components underlying options, stock index warrants, currency index warrants or currency warrant when such components are held in conjunction with certain positions in the overlying option or warrant. In respect of an option or warrant on a market index, an underlying stock basket is an eligible underlying component. The option or warrant must be listed or guaranteed by the carrying broker dealer. In the case of a call option or warrant carried in a short position, a related long position in the underlying component shall be valued at no more than the call option/warrant exercise price for margin equity purposes.

(a) *Long Option Offset.* When a component underlying an option or warrant is carried long (short) in [an]*the same* account [in which there is also carried]*as* a long put (call) option or warrant specifying equivalent units of the underlying component, the minimum amount of margin which must be maintained on the underlying component is 10% of the option/warrant exercise price plus the out-of-the-money amount not to exceed the minimum maintenance required pursuant to paragraph (b) of this Rule.

(b) *Conversion.* When a call option or warrant carried in a short position is covered by a long position in equivalent units of the underlying component and there is [also] carried *in the same account* a long put option or warrant specifying equivalent units of the same underlying component and having the same exercise price and expiration date as the short call option or warrant, the minimum amount of margin which must be maintained for the underlying component shall be 10% of the exercise price.

(c) *Reverse Conversion.* When a put option or warrant carried in a short position is covered by a short position in equivalent units of the underlying component and there is [also] carried *in the same account* a long call option or warrant specifying equivalent units of the same underlying component and having the same exercise price and expiration date as the short put option or warrant, the minimum amount of margin which must be maintained for the underlying component shall be 10% of the exercise price plus the amount by which the exercise price of the put exceeds the current market value of the underlying, if any.

(d) *Collar.* When a call option or warrant carried in a short position is covered by a long position in equivalent units of the underlying component and there is [also] carried *in the same account* a long put option or warrant specifying equivalent units of the same underlying component and having a lower exercise price than, and same expiration date as, the short call option/warrant, the minimum amount of margin which must be maintained for the underlying component shall be the lesser of 10% of the exercise price of the put plus the put out-of-the-money amount or 25% of the call exercise price.

(e) Protected Option. When an index call (put) option contract or warrant is carried in a short position (the ''protected option or warrant position'') and there is carried in the same account a long (short) position in an underlying stock basket, non-leveraged index mutual fund or non-leveraged exchange-traded fund (each, the ''protection'') that is based on the same index underlying the index option or warrant, the protected option or warrant position is not subject to the requirement set forth in subparagraph (c)(5)(A) above if the following conditions are met:

(1) when the protected option or warrant position is created, the absolute value of the protection is not less than 100% of the aggregate current underlying index value associated with the protected option or warrant position determined at either (A) the time the order that created the protected option or warrant position was entered or executed; or (B) the close of business on the trading day the protected option or warrant position was created;

(2) the absolute value of the protection is at no time less than 95% of the aggregate current underlying index value associated with the protected option or warrant position; and

(3) margin is maintained in an amount equal to the greater of: (A) the amount, if any, by which the aggregate current underlying index value is above (below) the aggregate exercise price of the protected call (put) option or warrant position; or (B) the amount, if any, by which the absolute value of the protection is below 100% of the aggregate current underlying index value associated with the protected option or warrant.

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change amends Rule 10.3 regarding margin requirements. Specifically, the Exchange proposes to amend Rule 10.3(c)(5)(C)(iii)(b) to update the provisions that provide margin relief for

a cash-settled index option written against a holding in an exchange-traded fund that tracks the same index as the index underlying the index option. Rule 10.3 sets forth margin requirements, and certain exceptions to those requirements, applicable to security positions of Trading Permit Holders' (''TPHs'') customers. Rule 10.3(c)(5)(C)(iii) currently requires no margin for covered calls and puts. Specifically, that rule provides the following:

- No margin is required for a call (put) option contract or warrant carried in a short position where there is carried in the same account a long (short) position in equivalent units of the underlying security.[3]
- No margin is required for a call (put) index option contract or warrant carried in a short position where there is carried in the same account a long (short) position in an (1) underlying stock basket,[4] (2) index mutual fund, (3) index portfolio receipt (''IPR''),[5] or (4) index portfolio share (''IPS''),[6] that is based on the same index underlying the index option or warrant and having a market value at least equal to the aggregate current index value.
- In order for the exceptions in the previous bullets to apply, in computing margin on positions in the underlying security, underlying stock basket, index mutual fund, IPR or IPS, as applicable,[7] (1) in the case of a call, the current market value to be used shall not be greater than the exercise price, and (2) in the case of a put, margin shall be the amount required by subparagraph (b)(2) of Rule 10.3, plus the amount, if any, by which the exercise price exceeds the current market value.

Rule 10.3(c)(5) generally requires TPHs to obtain from a customer, and maintain, a margin deposit for short cash-settled index options in an amount equal to 100% of the current market value of the option plus 15% (if overlying a broad-based index) or 20% (if overlying a narrow-based index) of the amount equal to the index value multiplied by the index multiplier minus the amount, if any, by which the option is out-of-the-money.[8] The minimum margin required for such an option is 100% of the option current market value plus 10% of the index value multiplied by the index multiplier for a call or 10% of the exercise price multiplied by the index multiplier for a put.

Pursuant to current Rule 10.3(c)(5)(C)(iii)(b) and (c), however, a TPH requires no margin deposit for a short cash-settled index call option if the TPH is holding in the same account a long position in an ETF that tracks the same index underlying the index option [9] if the current market value of the ETF for margin purposes (1) is at least equal to the aggregate current index value and (2) is not greater than the exercise price. If an account is short a cash-settled index put option and is holding in the same account a short position in the ETF, a TPH needs to require a margin deposit for the amount required by Rule 10.3(b)(2) [10] plus the amount, if any, by which the exercise price of the option exceeds the market value of the ETF if the market value of the ETF is at least equal to the aggregate current index value.

The Exchange proposes to amend this exception to margin requirements applicable to short option positions or warrants on indexes that are offset by positions in an underlying stock basket, non-leveraged index mutual fund, or non-leveraged exchange-traded fund (each, the ''protection'') that is based on the same index option, as well as move it within Rule 10.3 to Rule 10.3(c)(5)(C)(iv).[11] Specifically, the proposed rule change adopts the following as Rule 10.3(c)(5)(C)(iv)(e): [12]

(e) When an index call (put) option contract or warrant is carried in a short position (the ''protected option or warrant position'') and there is carried in the same account a long (short) position in an underlying stock basket, non-leveraged index mutual fund or non-leveraged exchange-traded fund (each, the ''protection'') that is based on the same index underlying the index option or warrant, the protected option or warrant position is not subject to the requirement set forth in subparagraph

[3] In computing margin on such a position in the underlying security, (a) in the case of a call, the current market value to be used shall not be greater than the exercise price and (b) in the case of a put, margin will be the amount required by Rule 10.3(b)(2), plus the amount, if any, by which the exercise price of the put exceeds the current market value of the underlying.

[4] An ''underlying stock basket'' means a group of securities that includes each of the component securities of the applicable index and which meets the following conditions: (a) the quantity of each stock in the basket is proportional to its representation in the index, (b) the total market value of the basket is equal to the underlying index value of the index options or warrants to be covered, (c) the securities in the basket cannot be used to cover more than the number of index options or warrants represented by that value and (d) the securities in the basket shall be unavailable to support any other option or warrant transaction in the account. *See* Rule 10.3(a)(7).

[5] IPRs are securities that (a) represent an interest in a unit investment trust (''UIT'') which holds the securities that comprise an index on which a series of IPRs is based; (b) are issued by the UIT in a specified aggregate minimum number in return for a ''Portfolio Deposit'' consisting of specified numbers of shares of stock plus a cash amount; (c) when aggregated in the same specified minimum number, may be redeemed from the UIT, which will pay to the redeeming holder the stock and cash then comprising the Portfolio Deposit; and (d) pay holders a periodic cash payment corresponding to the regular cash dividends or distributions declared and paid with respect to the component securities of the stock index on which the IPRs are based, less certain expenses and other charges as set forth in the UIT prospectus. IPRs are ''UIT interests'' within the meaning of the Rules. *See* Rule 1.1. A UIT Interest is any share, unit, or other interest in or relating to a unit investment trust, including any component resulting from the subdivision or separation of such an interest.

[6] IPSs are securities that (a) are issued by an open-end management investment company based on a portfolio of stocks or fixed income securities designed to provide investment results that correspond generally to the price and yield performance of a specified foreign or domestic stock index or fixed income securities index; (b) are issued by such an open-end management investment company in a specified aggregate minimum number in return for a deposit of specified number of shares of stock and/or a cash amount, or a specified portfolio of fixed income securities and/or a cash amount, with a value equal to the next determined net asset value; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such open-end management investment company, which will pay to the redeeming holder stock and/or cash, or a specified portfolio of fixed income securities and/or cash with a value equal to the next determined net asset value. *See* Rule 1.1.

[7] IPRs and IPSs are commonly referred to as ETFs.

[8] The out-of-the-money amount for a call is any excess of the aggregate exercise price of the option or warrant over the product of the current (spot or cash) index value and the applicable multiplier. The out-of-the-money amount for a put is any excess of the product of the current (spot or cash) index value and the applicable multiplier over the aggregate exercise price of the option or warrant.

[9] This is the same margin treatment that applies to an option on an equity security written against the underlying security. *See* current Rule 10.3(c)(5)(C)(iii)(a).

[10] Rule 10.3(b)(2) provides the minimum amount of margin that must be maintained in customer margin accounts having positions in securities is: (1) with respect to long positions, 25% of the current market value of all long in the account; plus (2) with respect to short positions, (a) $2.50 per share or 100% of the current market value, whichever is greater, of each security short in the account that has a current market value of less than $5.00 per share; plus (b) $5.00 per share or 30% of the current market value, whichever is greater, of each security short in the account that has a current market value of $5.00 per share or more.

[11] Proposed paragraph (e) limits the margin relief to index options written against an underlying stock basket, non-leveraged index mutual fund or non-leveraged exchange-traded fund (compared to underlying stock basket, index mutual fund, IPR, or IPS in current subparagraph (iii)(b)). The Exchange proposes to add the non-leveraged limitation to clarify that this exception is not intended to and does not apply to leveraged instruments. Additionally, the Exchange excludes IPRs and IPSs from being eligible for the margin relief in paragraph (e), as the Exchange understands that the use and availability of these products has diminished and has not observed the writing of index options against them.

[12] The proposed rule change identifies the strategy described in proposed subparagraph (e) as a ''protected option,'' which is a strategy of writing an index option against a holding in an ETF based on the same index as the index option, to differentiate it from a ''covered call,'' which is a strategy of writing an option against a position in an underlying security (the margin treatment for which is described in current subparagraph (iii)(a)).

(c)(5)(A) above if the following conditions are met:

(1) when the protected option or warrant position is created, the absolute value of the protection is not less than 100% of the aggregate current underlying index value associated with the protected option or warrant position determined at either (A) the time the order that created the protected option or warrant position was entered or executed; or (B) the close of business on the trading day the protected option or warrant position was created;

(2) the absolute value of the protection is at no time less than 95% of the aggregate current underlying index value associated with the protected option or warrant position; and

(3) margin is maintained in an amount equal to the greater of: (A) the amount, if any, by which the aggregate current underlying index value associated with the protected option or warrant position is above (below) the aggregate exercise price of the protected call (put) option or warrant position; or (B) the amount, if any, by which the absolute value of the protection is below the aggregate current underlying index value associated with the protected option or warrant position.

The proposed rule change provides that the margin requirement for an uncovered, short index option or warrant does not apply to a protected option or warrant position if certain conditions are met. The first proposed condition to qualify for the exception is that the TPH must carry or establish in the same account as the protected option or warrant position protection with an absolute value of not less than 100% of the aggregate underlying index value at either the time the order that created the protected option or warrant position was entered or executed or the close of business on the trading day the protected option or warrant position was created. This proposed first condition provides clearing brokers with flexibility regarding the point in time at which to value the protection. The aggregate underlying index value used would be that which existed at the same point in time the clearing broker selects to value the protection. This first condition corresponds to the concept of covered writing (such as writing a covered call). When writing a covered call, a market participant must have in the same account as the short call position a fully offsetting position in the underlying stock (in other words, 100% of the short position's aggregate underlying value, which is equal to the price of the stock times 100 (the number of shares underlying one option)).

The second proposed condition to qualify for the exception is that the absolute value of the protection must at no time be less than 95% of the aggregate underlying index value associated with the protected option or warrant position. Like the first proposed condition, this second proposed condition is intended to correspond to covered writing by requiring a market participant to maintain the protection in an amount close to the aggregate underlying index value associated with the protected option or warrant position. Because the value of the protection typically will not track exactly the aggregate underlying index value (*i.e.,* tracking error), the 95% threshold will require the absolute value of the protection to remain close to the aggregate underlying index value while effectively imposing a cap of 5% on how much the two values may diverge (*i.e.,* the value of the protection may not be more than 5% less than the value of the aggregate underlying index value). If the absolute value of the protection falls below 95% of the aggregate underlying index value associated with the protected option or warrant position, the protected option or warrant position would be deemed uncovered and thus no longer eligible for relief from the uncovered, short index option margin requirement. When that occurs, a clearing broker must either collect the required margin amount for the short index option or warrant position, require that the value of the protection be increased to the 100% of the aggregate underlying index value, or liquidate the short index option or warrant position.

The third proposed condition to qualify for the exception is to maintain margin in an amount equal to the greater of: (a) the amount, if any, by which the aggregate underlying index value associated with the protected option or warrant position is above (below) the aggregate exercise price of the protected call (put) option or warrant position; or (b) the amount, if any, by which the absolute value of the protection is below the aggregate underlying index value associated with the protected option or warrant (which would be subject to the 95% threshold imposed by the second proposed condition, as described above).

The proposed margin requirement to cover any difference by which the underlying index value is above (below) the exercise price of a call (put), in aggregate, would capture any amount by which a protected option or warrant position is in-the-money (*i.e.,* the amount the aggregate underlying index value exceeds the aggregate exercise price for a short call). Pursuant to this proposed requirement, margin equivalent to the in-the-money amount of the protected option or warrant position would need to be held in the account with that position, which would then be available to offset any debit to that account in the event of an exercise of the protected option or warrant. This corresponds to current Cboe Rule 10.3(c)(5)(C)(iii)(c), which requires the value of the protection or underlying stock to be capped at the exercise price of a covered call for no additional margin to be required for that call position. Both approaches prevent any in-the-money amount from contributing equity to the account and being used to support other positions.

The proposed alternative margin requirement to cover any difference by which the absolute value of the protection is below the aggregate underlying index value associated with the protected option or warrant would compensate for any tracking error. Pursuant to this proposed requirement, margin equivalent to the value of the divergence between the absolute value of the protection and the aggregate underlying index value would need to be maintained once a protected option or warrant position is created. However, this requirement would be rendered moot if the absolute value of the protection fell below 95% of the aggregate underlying index value associated with the protected option or warrant position, because the position at that point would be considered uncovered. To the extent equity is not available in the margin account to meet this requirement, a TPH can require its customer to deposit margin into the account. The Exchange believes this is more practical than requiring the value of the protection to be maintained at 100% of the aggregate underlying index value in actual shares (or applicable units) of the protection, as this would require continuous small transactions in the protection instrument to offset tracking differences (which are generally no larger than 2%).

Because there may be instances where margin requirements for the in-the-money amount and the tracking error may be duplicative,[13] the Exchange proposes to require only the greater amount of the two to avoid requiring an unnecessarily high amount of margin.

Currently, if the absolute value of the protection is less than the aggregate underlying index value, the protection position must be supplemented to address the deficiency. As proposed, such deficiency would require margin (to the extent such deficiency is not

[13] Two out of a total of six possible orderings of underlying index value, exercise price and protection value would result in overlapping margin requirements as proposed. For all others, one of the proposed margin requirement alternatives would be zero.

greater than 5%) in the form of available equity in the margin account or a deposit of margin in any form (*e.g.,* cash or marginable securities) rather than the purchase, sale, or deposit of additional protection to address a deficiency (regardless of the amount of the deficiency).[14] As a result, the proposed rule change will reduce the need for small and potentially frequent purchases, sales, or deposits of additional protection, which may reduce the operational cost of the protected option strategy for customers. While the structure of protection, particularly ETFs, and market forces may cause the protection's value to differ from the index value, the Exchange has observed that these values are generally highly correlated and thus do not deviate significantly. Therefore, the Exchange believes the proposed margin requirement for protected options is an effective safeguard against the risk of a short option position.

Additionally, the proposed rule change eliminates the requirement to mark the price of a long ETF with an index call option written against it at the lower of the ETF's market value or the index option strike price. With covered call options, this requirement is intended to cap favorable moves in the price of the underlying security at the strike price because moves above the strike price will not be realized. Currently, the Exchange applies this same requirement (as set forth in Rule 10.3(c)(5)(C)(iii)(c)) to protected options written against ETF holdings to maintain equivalency with the treatment of covered options. As an alternative, the proposed rule substitutes a margin requirement in this situation, which would require margin to be collected in an amount equal to, for example, the amount by which the aggregate underlying index value exceeds the aggregate exercise price in the case of a protected index call option or warrant position.

Further to the above, the proposed rule change deletes Rule 10.3(c)(5)(C)(iii)(b), as well as the cross-reference to such paragraph and the references to underlying stock basket, index mutual fund, IPR or IPS, as applicable,[15] in current subparagraph (c), as those terms relate specifically to current subparagraph (b). Because this would leave only one section in Rule 10.3(c)(5)(C)(iii), the proposed rule change deletes subparagraph lettering and combines current subparagraph (iii)(a) and current subparagraph (iii)(c) into a single provision as subparagraph (iii) and makes corresponding conforming changes.

The proposed rule change also makes clarifying, nonsubstantive changes in each subparagraph of Rule 10.3(c)(5)(C)(iv) to conform language in those subparagraphs to language used throughout Rule 10.3. Specifically, the proposed rule change amends the provision of each subparagraph to state that the minimum amount of required margin in the circumstances described in each subparagraph applies when the applicable long position is carried ''in the same account as'' the applicable short position, rather than ''also carried.'' This language is consistent with the language in, for example, current Rule 10.3(c)(5)(C)(iii), as margin requirements are determined generally based on positions held in the same account.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[18] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes the proposed rule change furthers the objectives of Section 6(c)(3) of the Act,[19] which authorizes the Exchange to, among other things, prescribe standards of financial responsibility or operational capability and standards of training, experience and competence for its Trading Permit Holders and person associated with Trading Permit Holders.

In particular, the proposed rule change amends a specific margin treatment related to short index options written against ETFs in the same manner. Given the difference described above between short stock options written against the underlying stock and short index options written against ETFs, the Exchange believes it is reasonable to apply different margin treatments to these different strategies. While the economic outcomes of covered options and protected options are similar, as described above, the Exchange believes it promotes just and equitable principles of trade to apply margin slightly differently to protected options than covered options. While the proposed rule change may result in lower margin requirements for protected option strategies, the Exchange believes the proposed floor on the value of protection and the margin amounts are more reasonable than the current requirements, as they are more tailored to these strategies and reflect the potential deficiencies between the value of the protection and the value of the index. As a result, the Exchange believes the proposed margin required will still be sufficient for protected option strategies. Given the high correlation between these values, the Exchange believes it is appropriate to require margin in an amount necessary to only cover this deficiency, as ultimately that is the risk against which the margin requirement is protecting. Furthermore, any amount by which the aggregate underlying index value is above (below) the aggregate exercise price of the option in the case of a call (put) (*i.e.,* the-in-the-money amount) would also be required as margin under the proposal. This in-the-money amount margin requirement prevents protection value in excess of the exercise price of the option (in the case of a short index call) from contributing to margin account equity and replaces the current requirement that caps the value of the protection at the aggregate exercise price of the option to qualify for a margin exception. The proposed rule change requires only the greater of the two margin requirements (the in-the-money amount or the protection deficiency amount) to apply to avoid requiring a customer to maintain unnecessarily high margin.

As noted above, the Exchange believes the proposed rule change may reduce the need for small and

[14] Pursuant to the current Rules, if the protection market value is not at least equal to the aggregate index value, and additional shares are not purchased or deposited, then the required margin is equal to the amount of the option current market value plus 15% (if a broad-based index) or 20% (if a narrow-based index) of the aggregate index value minus any out-of-the-money amount, subject to a minimum requirement.

[15] These terms are related only to current subparagraph (b).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *Id.*

[19] 15 U.S.C. 78f(c)(3).

potentially frequent purchases, sales, or deposits of additional protection, which may reduce the operational cost of the protected option strategy. As a result, the Exchange believes the proposed rule change may make this strategy more beneficial for customers and thus remove impediments to and perfect the mechanism of a free and open market, as well as reduce the margin required for such strategies, which will potentially free up capital that can be put back into the market, which ultimately benefits investors.

The proposed clarifying, nonsubstantive changes provide for more consistent language in similar rule provisions, which will ultimately benefit investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended as a competitive filing, but rather to modify margin requirements for a certain option strategy to be more reasonable and practical. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as it will apply the same margin treatment to all TPHs. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition, as several other options exchanges incorporate by reference the Exchange's margin rules into their rules (and thus apply them to their members), which incorporation by reference would apply to the proposed rule change if approved by the Commission. Additionally, as discussed above, the proposed rule change may reduce the operational burden of protected option strategies, as well as reduce the margin required for such strategies, which may make the strategies more beneficial for customers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2022–058 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2022–058. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2022–058 and should be submitted on or before December 23, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–26234 Filed 12–1–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17649 and #17650; Puerto Rico Disaster Number PR–00043]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 6.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Puerto Rico (FEMA–4671–DR), dated 09/29/2022.

Incident: Hurricane Fiona.

Incident Period: 09/17/2022 through 09/21/2022.

DATES: Issued on 11/28/2022.

Physical Loan Application Deadline Date: 11/28/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/29/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Puerto Rico, dated 09/29/2022, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Municipalities: Culebra, Loiza, Vieques

All other information in the original declaration remains unchanged.

[20] 17 CFR 200.30–3(a)(12).

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–26284 Filed 12–1–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17718 and #17719; West Virginia Disaster Number WV–00059]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of West Virginia

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of West Virginia (FEMA–4678–DR), dated 11/28/2022.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 07/12/2022 through 07/13/2022.

DATES: Issued on 11/28/2022.

Physical Loan Application Deadline Date: 01/27/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 08/28/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, 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 11/28/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: McDowell

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17718 B and for economic injury is 17719 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–26283 Filed 12–1–22; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36649]

Illinois Western Railroad Company—Operation Exemption—in Greenville, Ill.

Illinois Western Railroad Company (ILW), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate approximately thirteen hundred feet of existing trackage owned by the City of Greenville (City), extending from a connection with CSX Transportation, Inc., into the Alan E. Gaffner Industrial Park (formerly the Howard M. Wolf Business Park), in Greenville, Bond County, Ill. (the Greenville Track). The Greenville Track does not have mileposts.

This transaction is related to a concurrently filed verified notice of exemption in *3i RR Holdings GP LLC—Control Exemption—Effingham Railroad,* Docket No. FD 36650, in which 3i RR Holdings GP LLC, 3i Holdings Partnership L.P., 3i RR Intermediate Holdings LLC, 3i RR LLC, Regional Rail Holdings, LLC, Regional Rail Sub Holdings LLC, and Regional Rail, LLC, seek to control ILW upon ILW's becoming a Class III rail carrier, and to control two other Class III rail carriers.

According to the verified notice, ILW has conducted switching operations on the Greenville Track since 1996, but its notice of exemption filed that year to operate the Greenville Track was dismissed as not being within the Board's authority. *See Ill. W. R.R.—Change in Operator Exemption—City of Greenville, Ill.,* FD 32853 (STB served Jan. 30, 1996). ILW states that, in connection with the pending sale of ILW and two rail carriers, it is seeking to establish and resolve its status as a rail carrier, consistent with the Board's 1997 decision in *Effingham Railroad—Petition for Declaratory Order—Construction at Effingham, Ill.,* 2 S.T.B. 606 (1997), *aff'd sub nom. United Transportation Union* v. *STB,* 183 F.3d 606 (7th Cir. 1999). ILW further states that operations on the Greenville Track will continue under the current iteration of an operating agreement with the City, which was entered into in 2016.[1]

ILW certifies that its projected annual revenue will not exceed $5 million and that the proposed transaction will not result in ILW's becoming a Class I or II rail carrier. ILW states that the operating agreement between it and the City contains no restriction on ILW interchanging traffic with any rail carriers.

The earliest this transaction may be consummated is December 18, 2022, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 9, 2022.

All pleadings, referring to Docket No. FD 36649, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on ILW's representative, Michael J. Barron, Jr., Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to ILW, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 29, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Raina White,

Clearance Clerk.

[FR Doc. 2022–26276 Filed 12–1–22; 8:45 am]

BILLING CODE 4915–01–P

[1] Public and confidential versions of the operating agreement were filed with the verified notice. The confidential version was submitted under seal concurrent with a motion for protective order, which is addressed in a separate decision.

SURFACE TRANSPORTATION BOARD

60-Day Notice of Intent To Seek Extension of Approval: Class I Railroad Annual Report

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of the collection of Class I Railroad Annual Reports, as described below.

DATES: Comments on this information collection should be submitted by January 31, 2023.

ADDRESSES: Direct all comments to Chris Oehrle, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001, or to *PRA@stb.gov.* When submitting comments, please refer to ''Paperwork Reduction Act Comments, Class I Railroad Annual Report.''

FOR FURTHER INFORMATION CONTACT: For further information regarding this collection, contact Pedro Ramirez at (202) 245–0333 or *pedro.ramirez@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) the accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) 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, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Subjects: In this notice, the Board is requesting comments on the extension of the following information collection:

Description of Collection

Title: Class I Railroad Annual Report.

OMB Control Number: 2140–0009.

Form Number: R–1.

Type of Review: Extension without change.

Respondents: Class I railroads.

Number of Respondents: Seven.

Estimated Time per Response: No more than approximately 250 hours. This estimate includes time spent reviewing instructions; searching existing data sources; gathering and maintaining the data needed; completing and reviewing the collection of information; and converting the data from the carrier's individual accounting system to the Board's Uniform System of Accounts, which ensures that the information will be presented in a consistent format across all reporting railroads. In prior years, the estimate was higher, but many of these functions have become automated and more routine through the respondents' software programming. Thus, the time per response has been reduced, with additional technological efficiencies anticipated in the future.

Frequency of Response: Annual.

Total Annual Hour Burden: No more than approximately 1,750 hours annually.

Total Annual ''Non-Hour Burden'' Cost: The respondent carriers are required by statute to submit a copy of the annual report, signed under oath. *See* 49 U.S.C. 11145. A hard copy of the report is mailed to the agency at an estimated cost of $15.00 per respondent, resulting in a total annual non-burden-hour cost of approximately $105.00 for all seven respondents. No other non-hour costs for operation, maintenance, or purchase of services associated with this collection have been identified, as: (a) this collection will not impose start-up costs on respondents; and (b) an additional copy of the report in Excel format is submitted to the agency electronically.

Needs and Uses: Annual reports are required to be filed by Class I railroads under 49 U.S.C. 11145. The reports show operating expenses and operating statistics of the carriers. Operating expenses include costs for right-of-way and structures, equipment, train and yard operations, and general and administrative expenses. Operating statistics include such items as car-miles, revenue-ton-miles, and gross ton-miles. These reports are used by the Board, other Federal agencies, and industry groups to monitor and assess railroad industry growth, financial stability, traffic, and operations, and to identify industry changes that may affect national transportation policy. Information from these reports is also entered into the Uniform Railroad Costing System (URCS), which is the Board's general purpose costing methodology. URCS, which was developed by the Board pursuant to 49 U.S.C. 11161, is used as a tool in rail rate proceedings (in accordance with 49 U.S.C. 10707(d)) to calculate the variable costs associated with providing a particular service. The Board also uses information from this collection to more effectively carry out other regulatory responsibilities, including: acting on railroad requests for authority to engage in Board-regulated financial transactions such as mergers, acquisitions of control, and consolidations, *see* 49 U.S.C. 11323–24; analyzing the information that the Board obtains through the annual railroad industry waybill sample, *see* 49 CFR 1244; measuring off-branch costs in railroad abandonment proceedings, in accordance with 49 CFR 1152.32(n); developing the ''rail cost adjustment factors,'' in accordance with 49 U.S.C. 10708; and conducting investigations and rulemakings.

Under the PRA, a Federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Under 44 U.S.C. 3506(c)(2)(A), Federal agencies are required to provide, prior to an agency's submitting a collection to OMB for approval, a 60-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Information from certain schedules contained in these reports is compiled and published on the Board's website, *https://www.stb.gov/reports-data/economic-data/.* Information in these reports is not available from any other source.

Dated: November 29, 2022.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2022–26255 Filed 12–1–22; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36650]

3i RR Holdings GP LLC, 3i RR Holdings Partnership L.P., 3i RR Intermediate Holdings LLC, 3i RR LLC, Regional Rail Holdings, LLC, Regional Rail Sub Holdings LLC, and Regional Rail, LLC—Control Exemption—Effingham Railroad Company, Illinois Western Railroad Company, and South Point & Ohio Railroad, Inc.

3i RR Holdings GP LLC, 3i RR Holdings Partnership L.P., 3i RR Intermediate Holdings LLC, 3i RR LLC, Regional Rail Holdings, LLC, and

Regional Rail Sub Holdings LLC (collectively, 3i RR) and Regional Rail, LLC (Regional Rail), both noncarriers, have filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Effingham Railroad Company (EFRR) and South Point & Ohio Railroad, Inc. (SPOR), both Class III carriers, and to acquire control of Illinois Western Railroad Company (ILW), a noncarrier, upon ILW's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *Illinois Western Railroad—Operation Exemption—in Greenville, Ill.,* Docket No. FD 36649, in which ILW seeks to operate approximately thirteen hundred feet of trackage owned by the City of Greenville, in Greenville, Bond County, Ill.

According to the verified notice, Regional Rail is directly controlled by Regional Rail Sub Holdings LLC, which is controlled by Regional Rail Holdings, LLC, which is controlled by 3i RR LLC, which is controlled by 3i RR Intermediate Holdings LLC, which is controlled 3i RR Holdings Partnership L.P., which is controlled by 3i RR Holdings GP LLC. The verified notice states that Regional Rail is a non-carrier holding company that directly controls the following eight Class III railroads: (1) Carolina Coastal Railway, Inc., which operates in North Carolina and South Carolina; (2) East Penn Railroad, LLC, which operates in Delaware and Pennsylvania; (3) Florida Central Railroad Company, Inc., which operates in Florida; (4) Florida Midland Railroad Company, Inc., which operates in Florida; (5) Florida Northern Railroad Company, Inc., which operates in Florida; (6) Middletown & New Jersey Railroad, LLC, which operates in New York; (7) Port Manatee Railroad LLC, which operates in Florida, and (8) Tyburn Railroad LLC, which operates in Pennsylvania.[1]

According to the verified notice, pursuant to a stock purchase agreement dated November 10, 2022, with respect to EFRR and ILW, and a stock purchase agreement to be entered into with respect to SPOR, Regional Rail proposes to acquire all of the stock of EFRR, ILW, and SPOR and assume direct control of those rail carriers. 3i RR and Regional Rail state that the stock purchase agreements do not include any provision that would limit the future interchange of traffic with a third-party connecting carrier.[2]

3i RR and Regional Rail represent that: (1) the rail lines of EFRR, ILW, and SPOR do not connect with the rail lines of any of the other rail carriers controlled by 3i RR and Regional Rail; (2) the transaction is not part of a series of anticipated transactions that would result in such a connection; and (3) the transaction does not involve a Class I rail carrier. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2).

This transaction may be consummated on or after December 18, 2022, the effective date of the exemption (30 days after the verified notice was filed).

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, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 9, 2022.

All pleadings, referring to Docket No. FD 36650, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on 3i RR's and Regional Rail's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to 3i RR and Regional Rail, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 29, 2022.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Raina White,

Clearance Clerk.

[FR Doc. 2022–26277 Filed 12–1–22; 8:45 am]

BILLING CODE 4915–01–P

[1] *See 3i Holdings GP LLC—Continuance in Control Exemption—Port Manatee R.R.,* FD 36553 (STB served Nov. 21, 2022).

[2] Public and confidential versions of the stock purchase agreements were filed with the verified notice. The confidential versions were submitted under seal concurrent with a motion for protective order, which is addressed in a separate decision.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Airport Land at the Toccoa-Stephens County Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA proposes to rule and invites public comment on the request to release .73 acres of federally obligated airport property at the Toccoa-Stephens County Airport.

DATES: Comments must be received on or before January 3, 2023.

ADDRESSES: Comments on this notice may be mailed or delivered in triplicate to the FAA to the following address: Atlanta Airports District Office Attn: Joseph Robinson, Planner, 1701 Columbia Ave., Suite 220, College Park, GA 30337.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to the Toccoa-Stephens County Airport Authority, Attn: Ms. Amber McCall, P.O. Box 494, Toccoa, GA 30577.

FOR FURTHER INFORMATION CONTACT: Joseph Robinson, Airport Planner, Atlanta Airports District Office, 1701 Columbia Ave., Suite 220, College Park, Georgia 30337–2747, (404) 305–6749. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release a parcel of land totaling 0.73 acres at the Toccoa-Stephens County Airport. The FAA determined this request to release submitted by the Sponsor meets the procedural requirements of the FAA and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

Issued in Atlanta, Georgia, on November 28, 2022.

Joseph Parks Preston,

Assistant Manager, Atlanta Airports District Office, Southern Region.

[FR Doc. 2022–26215 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0047; Notice 2]

Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Cooper Tire & Rubber Company (Cooper Tire), has determined that certain Cooper CS5 Grant Touring and Cooper Evolution Tour replacement passenger car tires do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* Cooper Tire filed a noncompliance report dated April 28, 2021, and subsequently, Cooper Tire petitioned NHTSA on May 12, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the grant of Cooper Tire's petition.

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview

Cooper Tire has determined that certain Cooper CS5 Grand Touring and Cooper Evolution Tour replacement passenger car tires do not fully comply with the requirements of paragraph S5.5.1(b) of FMVSS No. 139, *New Pneumatic Radial Tires for Light Vehicles* (49 CFR 571.139). Cooper Tire filed a noncompliance report dated April 28, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Cooper Tire subsequently petitioned NHTSA on May 12, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of Cooper Tire petition was published with a 30-day public comment period, on May 16, 2022, in the **Federal Register** (87 FR 29779). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2021–0047.''

II. Tires Involved

Approximately 294 Cooper CS5 Grand Touring, size 225/50R18, and Cooper Evolution Tour, size 225/60R16, replacement passenger car tires, manufactured between February 14, 2021, and March 27, 2021, are potentially involved.

III. Noncompliance

Cooper Tire explains that the subject tires were molded with an upside down and backwards serial week and year on the outboard sidewall and do not comply with the requirements set forth in paragraph S5.5.1(b) of FMVSS No. 139.

IV. Rule Requirements

Paragraph S5.5.1(b) of FMVSS No. 139 includes the requirements relevant to this petition.

- Each tire must be labeled with the tire identification number required by 49 CFR part 574, which includes the date code consisting of the week and year of manufacture, on the intended outboard sidewall of the tire.

V. Summary of Cooper Tire's Petition

The following views and arguments presented in this section, ''V. Summary of Cooper Tire's Petition,'' are those of Cooper Tire. They do not reflect the views of the Agency. Cooper Tire describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Cooper Tire submitted the following reasoning:

1. The tires subject to this petition, on their outboard side only, were molded with an upside down and backwards DOT serial week and year. The serial number stampings should read: DOT U9 X3 1 LP 0721 and UP 78 1CW 1221. The outboard side, which includes the date code, was molded with the date code information oriented incorrectly upside down and backwards, which resulted in the characters being out of proper sequence.

2. Cooper contends that the 294 tires subject to this petition meet and/or exceed all performance requirements and all other labeling markings as required by FMVSS No. 139.

3. Furthermore, Cooper Tire says that is not aware of any crashes, injuries, customer complaints, or field reports associated with the subject tires involved in this petition.

4. Cooper Tire believes that the upside down and backward date code will not cause confusion for the consumer or dealer that is selecting and mounting the tire, as the error is quite obvious, and there is no logical reading or interpretation of the date code in its upside down and backward position. Cooper Tire also believes that consumers and dealers will easily be able to see the issue and correctly identify the date code.

5. Cooper believes the following NHTSA statements, taken from another petition, apply to its petition: ''The purpose of the date code is to identify a tire so that, if necessary, the appropriate action can be taken in the interest of public safety—such as a safety recall notice.'' *See* Bridgestone/Firestone, Inc., 64 FR 29,080 (May 28, 1999); *see also* Cooper Tire & Rubber Company, 68 FR 16,115 (April 2, 2003). Furthermore, Cooper feels the following NHTSA statement applies to its petition, ''[t]he agency believes that the true measure of inconsequentiality to motor vehicle safety in this case is the effect of the noncompliance on the ability of the tire manufacturer to identify the tires in the event of recall.'' *See* Bridgestone/Firestone, Inc., 66 FR 45,076 (Aug. 27, 2001).

6. Cooper also stated that NHTSA has granted petitions and found that TIN noncompliance is inconsequential to safety in cases where the TIN is out of sequence or mislabeled. *See,* Bridgestone/Firestone North America Tire, LLC, 71 FR 4396 (Jan. 26, 2006) (granting petition where date code was missing because manufacturer could still identify and recall the tires); Cooper Tire & Rubber Company, 68 FR 16,115 (April 2, 2003) (granting petition where tires were labeled with wrong plant code, because ''the tires have a unique DOT identification''); Bridgestone/Firestone, Inc., 66 FR 45,076 (Aug. 27, 2001) (granting petition where the date code was labeled incorrectly, because ''the information included on the tire identification label and the manufacturer's tire production records is sufficient to ensure that these tires can be identified in the event of a recall''); Bridgestone/Firestone, Inc., 64 FR 29,080 (May 28, 1999) (granting petition where the wrong year was marked in date code on the tires); Cooper Tire & Rubber Company; 63 FR 29,059 (May 27, 1998) (granting petition where date code was missing where tires had a unique TIN for recall purposes); Bridgestone/Firestone, Inc., 60 FR 57,617 (Nov. 16, 1995) (granting petition where date code was out of sequence); Uniroyal Goodrich Tire Company, 59 FR 64,232 (Dec. 13, 1994)

(granting petition where week and year were mislabeled on tires).

Cooper Tire concludes that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that its petition requesting exemption from providing notification of the noncompliance, as required by 49 U.S.C. 30118, as well as a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. NHTSA's Analysis

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in an FMVSS—as opposed to a *labeling requirement with no performance implications*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[1]

In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.[2] In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.[3]

NHTSA has evaluated and analyzed the merits of the inconsequential noncompliance petition submitted by Cooper Tire and agrees that, based on the information presented, is granting Cooper's request for relief from notification and remedy based on the following:

- *Operational Safety & Performance:* NHTSA reviewed the data Cooper provided and noted the subject tires comply with FMVSS No. 139 test criteria.
- *Traceability & Identification:* NHTSA agrees that in this case, the upside down and backwards date code in the TIN does not appear to affect the ability of the manufacturer or consumer to register or identify the affected tires in the event of a recall. After reviewing a sample,[4] the Agency agrees that the date code is legible because this portion of the TIN is visually separated from the rest of the TIN and the font style is such that the characters are obvious even when rotated 180 degrees from nominal. The obvious error allows for an accurate reading of the full TIN if/when registering and/or recalling the tires in the future.

VII. NHTSA's Decision

In consideration of the foregoing, NHTSA finds that Cooper Tire has met its burden of persuasion that the subject FMVSS No. 139 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, Cooper Tire's petition is hereby granted, and Cooper Tire is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that Cooper Tire no longer controlled at the time it determined that the noncompliance existed. However, the grant of this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Cooper Tire notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–26271 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0021; Notice 2]

Mercedes-Benz USA, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Mercedes-Benz AG (MBAG) and Mercedes-Benz USA, LLC (MBUSA) (collectively, ''Mercedes-Benz'') have determined that certain model year (MY) 2019 Mercedes-Benz A-Class motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 104, *Windshield Wiping and Washing Systems.* Mercedes-Benz filed a noncompliance report dated February 24, 2020. Mercedes-Benz subsequently petitioned NHTSA on March 12, 2020, and later provided supplemental material on July 9, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the grant of Mercedes-Benz's petition.

FOR FURTHER INFORMATION CONTACT: Neil Dold, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–7352, facsimile (202) 366–3081.

SUPPLEMENTARY INFORMATION:

I. Overview

Mercedes-Benz has determined that certain MY 2019 Mercedes-Benz A-Class motor vehicles do not fully comply with the requirements of paragraph S4.1.2 of FMVSS No. 104, *Windshield Wiping and Washing Systems* (49 CFR 571.104). Mercedes-Benz filed a noncompliance report dated February 24, 2020, pursuant to 49 CFR part 573, *Defect and noncompliance responsibility and reports.* Mercedes-Benz subsequently petitioned NHTSA on March 12, 2020, and later provided supplemental material on July 9, 2020, for an exemption from the notification and remedy requirements of 49 U.S.C.

[1] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[2] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[3] *See Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016); *see also United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[4] A photo of the subject noncompliance can be found in Cooper Tire's petition at *https://www.regulations.gov/document/NHTSA-2021-0047-0001.*

chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for inconsequential defect or noncompliance.*

Notice of receipt of Mercedes Benz's petition was published with a 30-day public comment period, on June 12, 2020, in the **Federal Register** (85 FR 35990). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2020–0021.''

II. Vehicles Involved

Approximately 4,145 MY 2019 Mercedes-Benz A220 and A220 4MATIC motor vehicles manufactured between August 3, 2018, and November 26, 2019, are potentially involved.

III. Noncompliance

Mercedes-Benz explains that the noncompliance is that the windshield wiping systems in the subject vehicles do not wipe the percentage of the windshield as required by paragraph S4.1.2 of FMVSS No. 104. Specifically, because of variations in the manufacturing process, the windshield wiping system may not meet the manufacturer's design specifications and thus may only wipe 93.8% of Area B of the windshield instead of the 94% minimum required.

IV. Rule Requirements

Paragraph S4.1.2 of FMVSS No. 104 includes the requirements relevant to this petition. When tested wet in accordance with SAE Recommended Practice J903a (1966), each passenger car windshield wiping system shall wipe the percentage of designated Areas A, B, and C of the windshield (established in accordance with S4.1.2.1) that (1) is specified in column 2 of the applicable table following subparagraph S4.1.2.1 and (2) is within the area bounded by a perimeter line on the glazing surface 25 millimeters from the edge of the ''daylight opening.''

V. Summary of Mercedes-Benz's Petition

The following views and arguments presented in this section, ''V. Summary of Mercedes-Benz's Petition,'' are the views and arguments provided by Mercedes-Benz and do not reflect the views of the Agency. Mercedes-Benz described the subject noncompliance and contended that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Mercedes-Benz submitted the following:

1. Mercedes-Benz cited the definition of ''motor vehicle safety'' as cited in the National Traffic and Motor Vehicle Safety Act of 1966 and their belief is that this matter is appropriate for a decision that the noncompliance is inconsequential to motor vehicle safety as it does not present any increased risk to vehicle occupants.

2. They state that, in the subject vehicles, the portion of the windshield that falls just below the minimum wiped area is located at the outer edge of the windshield. In the worst-case scenario, only 93.8%, instead of the minimum 94%, of the Area B portion of the windshield remains *wiped* (*note:* the petition erroneously stated ''unwiped'' rather than ''wiped''). In the original petition, Mercedes-Benz stated that the affected portion of Area B is located at the outer edge of the passenger's side of the windshield; however, in a subsequent communication with NHTSA, they clarified that the affected portion of Area B is located at the outer edge of the driver's side of the windshield rather than the passenger's side.

3. Mercedes-Benz asserts that NHTSA has previously considered the performance of windshield wiper systems in the context of interpreting the meaning of the term ''daylight opening'' in FMVSS No. 104. Mercedes-Benz says that in 2003, in response to a request from a manufacturer, NHTSA interpreted that opaque coatings located around the edge of the windshield would not be considered part of the daylight opening for purposes of calculating the starting point of the wiped area. *See* Letter to Reed, May 6, 2003. This interpretation was an apparent change in approach for several manufacturers. In a request for reconsideration, the industry reported that many vehicles would not meet the minimum wiped portion of Area B based on the Agency's new interpretation. In supporting comments, two manufacturers reported that there were multiple vehicle models that would not meet the 94% minimum requirement for Area B. For one of the manufacturers, all of its vehicles were no more than 93.2% of the Area B minimum, while the other manufacturer did not provide specific information on how far its system deviated from the Area B minimum. After considering the substantial resources necessary to redesign the wiper systems outside of the normal vehicle refresh schedule, the Agency delayed the date on which it would begin enforcement of FMVSS No. 104 based on its updated interpretation. *See* Letter to Strassburger, January 7, 2005.

4. Thus, while the Agency was alerted to the fact that certain vehicles would not be able to comply with the minimum wiped area requirements of FMVSS No. 104, the Agency delayed implementing enforcement of the new interpretation for several years. While the delay was based, in part on the additional complexities needed to update the vehicle, fundamentally, the small deviation in the minimum wiped area requirement appears to not have been considered one that adversely impacted driver visibility or increased the safety risk to vehicle occupants. In that case, the deviation from the minimum wiped portion of Area B was more than what exists in the subject vehicles. While it is unclear from the interpretation letters what portion of Area B did not meet the minimum wiped requirements, in the subject vehicles, only a narrow strip of a portion of the outer edge of the driver's side of the windshield is affected by the deviation. Due to the location and small size of the unwiped area, the deviation would not affect the visibility of the driver or their ability to safely operate the vehicle and would not lead to an overall increased safety risk to the vehicle occupants.

5. Mercedes-Benz stated that the windshield wiper systems installed in the subject vehicles otherwise meet or exceed the remaining requirements in FMVSS No. 104 for the wiped portion of Areas A and C, for wiper frequency, and the windshield washing system. Mercedes-Benz has not received any reports related to a lack of visibility due to the performance of the windshield wiping system at issue here.

Mercedes-Benz concluded by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

Mercedes Benz's complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at: *https://www.regulations.gov* and by following the online search instructions to locate the docket number as listed in the title of this notice.

VI. NHTSA's Analysis

The burden of establishing the inconsequentiality of a failure to comply

with a *performance requirement* in a standard—as opposed to a *labeling requirement with no performance implications*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[1] Potential performance failures of safety-critical equipment, like seat belts or air bags, are rarely deemed inconsequential.

An important issue to consider in determining inconsequentiality based upon NHTSA's prior decisions on noncompliance issues was the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[2] NHTSA also does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety. ''Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [3] ''[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [4]

Arguments that only a small number of vehicles or items of motor vehicle equipment are affected have also not justified granting an inconsequentiality petition.[5] Similarly, NHTSA has rejected petitions based on the assertion that only a small percentage of vehicles or items of equipment are likely to actually exhibit a noncompliance. The percentage of potential occupants that could be adversely affected by a noncompliance does not determine the question of inconsequentiality. Rather, the issue to consider is the consequence to an occupant who is exposed to the consequence of that noncompliance.[6] These considerations are also relevant when considering whether a defect is inconsequential to motor vehicle safety.

NHTSA has evaluated the merits of the inconsequential noncompliance petition submitted by Mercedes-Benz and has determined that this particular noncompliance is inconsequential to motor vehicle safety. Specifically, the Agency considered the following when making its decision:

1. Given the inconsistent information in the petition about which portions of the windshield did not meet the Standard, NHTSA requested additional information from Mercedes-Benz. On July 9, 2020, Mercedes-Benz responded, and the supplemental information provided is available on the FDMS website.[7] In the worst-case scenario presented in this data, Area C is completely (100%) wiped, as required by the standard. Area A, according to this data, has a wiped area of 91%—exceeding the standard's minimum threshold of 80%—while the wiped portion of Area B is slightly below the required minimum 94% threshold at 93.8%.

2. The magnitude of the deviation from Mercedes-Benz's design specification was also considered. Vehicles manufactured without deviation from Mercedes-Benz's specification would have wiped 91.4% of Area A and 94.3% of Area B. In the worst-case scenario described by Mercedes-Benz, comparing the manufacturing deviation to Mercedes-Benz's design specification, the percent of Area A wiped decreases by 0.4% to the aforementioned 91% of Area A's total area and the percent of Area B wiped decreases by 0.5% to the aforementioned 93.8% of Area B's total area. There is no change in the wiped portion of Area C (the area of the windshield directly in front of the driver).

3. NHTSA also considered the location within Area B affected by the manufacturing deviation. The reduction in wiped area is located at the outer edge of Area B on the driver's side—with greater deviation in wiper coverage toward the top of the windshield—where the impact to visibility is less likely to create a safety risk. A depiction of the wiper deviation was provided by Mercedes-Benz in the petition and was updated on July 9, 2020, after NHTSA requested additional information. Both depictions are available on the FDMS website.

4. Although Mercedes-Benz's petition cited a letter of interpretation that delayed enforcement of the threshold for minimum wiped area for Area B, NHTSA did not consider this to be persuasive. The delay at issue resulted from the agency's determination that strict enforcement would be inequitable. NHTSA did not determine that the requirements of the Standard should be relaxed. Our analysis here is based on the location and magnitude of the specific noncompliance as detailed in this notice and the documents included in the docket.

5. NHTSA has determined, based on both the magnitude and the location of the wiper deviation, that the difference between a compliant vehicle (produced without the manufacturing deviation) and a worst-case noncompliant vehicle (produced with the manufacturing deviation) is unlikely to impact visibility in a manner that would be consequential to safety.

VII. NHTSA's Decision

In consideration of the foregoing, NHTSA finds that Mercedes-Benz has met its burden of persuasion that the subject FMVSS No. 104 noncompliance in the affected vehicles is inconsequential to motor vehicle safety. Accordingly, Mercedes-Benz's petition is hereby granted, and Mercedes-Benz is exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject vehicles that Mercedes-Benz no longer

[1] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[2] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[3] *Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[4] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[5] *See Mercedes-Benz, U.S.A., L.L.C.; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38342 (July 23, 2001) (rejecting argument that noncompliance was inconsequential because of the small number of vehicles affected); *Aston Martin Lagonda Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 41370 (June 24, 2016) (noting that situations involving individuals trapped in motor vehicles—while infrequent—are consequential to safety); *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21664 (Apr. 12, 2016) (rejecting argument that petition should be granted because the vehicle was produced in very low numbers and likely to be operated on a limited basis).

[6] *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco Inc.; Denial of Application for Decision of Inconsequential Noncompliance,* 64 FR 29408, 29409 (June 1, 1999).

[7] *Regulations.gov/docket/NHTSA-2020-0021.*

controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Mercedes-Benz notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–26270 Filed 12–1–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: CMIA Annual Report and Direct Cost Claims

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the CMIA Annual Report and Direct Cost Claims.

DATES: Written comments should be received on or before January 31, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: CMIA Annual Report and Direct Cost Claims.

OMB Number: 1530–0066.

Form Number: None.

Abstract: States and Territories must report interest owed to and from the Federal government for major Federal assistance programs on an annual basis. The data is used by Treasury and other Federal agencies to verify State and Federal interest claims, to assess State and Federal cash management practices and to exchange amounts of interest owed.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 56.

Estimated Time per Respondent: Average 393.5 hours per state.

Estimated Total Annual Burden Hours: 22,036.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. 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; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 18, 2022.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2022–26220 Filed 12–1–22; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 706–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning United States Additional Estate Tax Return.

DATES: Written comments should be received on or before January 31, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please reference the information collection's ''OMB number 1545–0116'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington, at (202)317–5744, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *sara.l.covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: United States Additional Estate Tax Return.

OMB Number: 1545–0016.

Form Number: 706–A.

Abstract: Form 706–A is used by individuals to compute and pay the additional estate taxes due under Code section 2032A(c). IRS uses the information to determine that the taxes have been properly computed. The form is also used for the basis election of section 1016(c)(1).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 180.

Estimated Time per Respondent: 1 hour, 19 minutes.

Estimated Total Annual Burden Hours: 1,678.

The following paragraph applies to all of the collections of information covered by this notice:

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 OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (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 respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 28, 2022.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2022–26258 Filed 12–1–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Occupational Tax and Registration Return for Wagering

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning occupational tax and registration return for wagering.

DATES: Written comments should be received on or before January 31, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov*. Include OMB control number 1545–0236 or Occupational Tax and Registration Return for Wagering.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Occupational Tax and Registration Return for Wagering.

OMB Number: 1545–0236.

Form Number: 11–C.

Abstract: Form 11–C is used to register persons accepting wagers, as required by Internal Revenue Code section 4412. The IRS uses this form to register the respondent, collect the annual stamp tax imposed by Code section 4411, and to verify that the tax on wagers is reported on Form 730, Monthly Tax Return for Wagers.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 11,500.

Estimated Time per Respondent: 7 hours, 4 minutes.

Estimated Total Annual Burden Hours: 81,190 hours.

The following paragraph applies to all the collections of information covered by this notice.

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 OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (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 respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 29, 2022.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2022–26310 Filed 12–1–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0784]

Agency Information Collection Activity: Application for Pre-Need Determination of Eligibility for Burial

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The National Cemetery Administration (NCA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine a claimant's eligibility for burial at a National Cemetery.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 31, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian Hurley, National Cemetery Administration (42E), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *NCA42EACTION@va.gov.* Please refer to ''OMB Control No. 2900–0784'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0784'' 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, NCA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of NCA's functions, including whether the information will have practical utility; (2) the accuracy of NCA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 2402; Public Law 103–446.

Title: Application for Pre-Need Determination of Eligibility for Burial, VA Form 40–10007.

OMB Control Number: 2900–0784.

Type of Review: Extension of a currently approved collection.

Abstract: This information (VA Form 40–10007) is used to collect information from Veterans and service members who wish to determine their eligibility for burial in a VA national cemetery prior to their time of need for planning purposes. The data will be used for this purpose. 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.

Affected Public: Individuals or households.

Estimated Annual Burden: 15,800 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 47,400.

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. 2022–26246 Filed 12–1–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0154]

Agency Information Collection Activity: Application for VA Education Benefits; Application for Family Member To Use Transferred Benefits; Application for VA Benefits Under the National Call to Service Program

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 January 31, 2023.

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. 2900–0154'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0154'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3034; 3241, 3323(a), 3471, 5101(a); Pub. L. 96–342, section 903; 10 U.S.C. and section 16131.

Title: Application For VA Education Benefits; Application For Family Member To Use Transferred Benefits; Application For VA Benefits Under The National Call To Service Program, VAFs 22–1990; 1990E and 1990N.

OMB Control Number: 2900–0154.

Type of Review: Revision of a currently approved collection.

Abstract: Applicants complete and submit the Application For Education Benefits, VA Form 22–1990; National Call to Service (NCS), VA Form 22–1990N, or the Transfer of Entitlement (TOE), VA Form 22–1990E to file their claim for VA education benefits, which all have different eligibility requirements. The information requested on each of these forms helps VA to determine the applicant's eligibility to education benefits.

Affected Public: Individuals or households.

Estimated Annual Burden: 170,780 hours.

Estimated Average Burden Time per Respondent: 15 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 683,122.

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. 2022–26312 Filed 12–1–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

42 CFR Part 2
45 CFR Part 164
Confidentiality of Substance Use Disorder (SUD) Patient Records; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2

45 CFR Part 164

RIN 0945–AA16

Confidentiality of Substance Use Disorder (SUD) Patient Records

AGENCY: Office for Civil Rights (OCR), 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: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') is issuing this notice of proposed rulemaking (NPRM) to solicit public comment on its proposal to modify its regulations to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

DATES: Comments due on or before January 31, 2023.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at *http://www.regulations.gov* by searching for the Docket ID number HHS–OCR–0945–AA16. Follow the instructions at *http://www.regulations.gov* for submitting electronic comments. Attachments should be in Microsoft Word or Portable Document Format (PDF).
- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, *Attention:* SUD Patient Records, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

Inspection of Public Comments: All comments received by the accepted methods and due date specified above may be posted without change to content to *http://www.regulations.gov,* which may include personal information provided about the commenter, and such posting may occur after the closing of the comment period. However, the Department may redact certain content from comments before posting, including threatening language, hate speech, profanity, graphic images, or individually identifiable information about a third-party individual other than the commenter.

Because of the large number of public comments normally received on **Federal Register** documents, OCR is not able to provide individual acknowledgments of receipt.

Please allow sufficient time for mailed comments to be received timely in the event of delivery or security delays.

Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. In addition, comments that are labeled as confidential business information or whose disclosure to the public is restricted by statute will not be accepted.

Docket: For complete access to background documents or posted comments, go to *http://www.regulations.gov* and search for Docket ID number HHS–OCR–0945–AA16.

FOR FURTHER INFORMATION CONTACT: Lester Coffer at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION: The discussion below includes an Executive Summary and overview describing the need for the proposed rules, a description of the statutory and regulatory background of the proposed rules, a section-by-section description of the proposed modifications, and the impact statement and other required regulatory analyses. The Department solicits public comment on all aspects of the proposed rules. Persons interested in commenting on the provisions of the proposed rules can assist the Department by preceding discussion of any particular provision or topic with a citation to the section of the proposed rule being discussed.

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Executive Summary

Overview

In this Notice of Proposed Rulemaking (NPRM), the Department proposes to modify certain provisions of part 2 of title 42 of the Code of Federal Regulations (42 CFR part 2 or ''Part 2'') [1] to implement statutory amendments to section 290dd–2 of title 42 United States Code (42 U.S.C. 290dd–2) enacted in section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[2]

Part 2 currently imposes different requirements for substance use disorder (SUD) treatment records protected by Part 2 (''Part 2 records'') [3] than the Health Insurance Portability and Accountability Act of 1996 (HIPAA) [4] Privacy, Security, Breach Notification, and Enforcement Rules (''HIPAA Rules'') [5] apply to protected health information (PHI).[6] The statutory and regulatory schemes apply to different types of entities and create dual obligations and compliance challenges for HIPAA covered entities [7] and business associates [8] that maintain PHI and Part 2 records, and thus are subject to both sets of rules.[9] Treatment providers have also expressed concerns that they lack access to complete information when treating patients.[10] Section 290dd–2, as amended by section 3221 of the CARES Act, aligns certain Part 2 requirements more closely to requirements of the HIPAA Rules to improve the ability of entities that are subject to Part 2 to use and disclose Part 2 records and makes other changes to Part 2, as described in this preamble.

Paragraphs (b), (c), and (f) of section 290dd–2, as amended by section 3221 of the CARES Act, contain modified or new requirements for patient consent and redisclosure of Part 2 records; [11] new rights to obtain an accounting of disclosures made with consent [12] and to request restrictions on disclosures; [13] greater restrictions against the use and disclosure of records in civil, criminal, administrative, and legislative proceedings against patients; [14] and new civil money penalties (CMPs) for violations of Part 2.[15] Paragraphs (i), (j), and (k) of section 290dd–2, as amended by section 3221 of the CARES Act, add new requirements to prohibit discrimination,[16] impose breach notification obligations,[17] and incorporate definitions from the HIPAA Rules into Part 2.[18] Finally, section 3221(i) of the CARES Act requires the Department to update its Notice of Privacy Practices (NPP) requirements in the HIPAA Privacy Rule (''Privacy Rule'') at 45 CFR 164.520 to address uses and disclosures of Part 2 records and individual rights with respect to those records.[19] This NPRM contains proposals to implement the CARES Act provisions relating to health information privacy; the Department intends to develop a separate rulemaking to implement the CARES Act antidiscrimination prohibitions.

In addition to changes mandated by the CARES Act, the Department proposes to address concerns about potential unintended consequences for government agencies of the change in enforcement authority and penalties for violations of Part 2. Specifically, the Department proposes to create a limitation on liability for agencies and persons acting on their behalf, that investigate and prosecute Part 2 programs (to be defined as ''investigative agencies'') and unknowingly receive records subject to Part 2 before applying for the requisite

[1] 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.

[2] Public Law 116–136, 134 Stat. 281 (March 27, 2020).

[3] *See* 42 U.S.C. 290dd–2(a). ''Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b)''.

[4] *See* the Administrative Simplification provisions of title II, subtitle F, of HIPAA (Public Law 104–191), 110 Stat. 1936 (August 21, 1996) which added a new part C to title XI of the Social Security Act (secs.1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, 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 (February 17, 2009).

[5] *See* the Privacy Rule, 45 CFR parts 160 and 164, subparts A and E; the Security Rule 45 CFR parts 160 and 164, subparts A and C; the Breach Notification Rule, 45 CFR part 164, subpart D; and the 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] 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'').

[8] 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'').

[9] *See* ''Part 2 Proposed Rule Brings Clarity and Reduces Regulatory Burdens for Substance Use Disorder Providers, but Challenges Remain'' (September 2019), *https://www.mintz.com/insights-center/viewpoints/2146/2019-09-part-2-proposed-rule-brings-clarity-and-reduces-regulatory;* ''HIPAA: A Trap for the Unwary'' (May 2014), *https://www.dykema.com/resources-alerts-HIPAA-A-Trap-for-the-Unwary_5-2014.html;* and correspondence from Partnership to Amend 42 CFR part 2 (March 2019), *https://www.pcpcc.org/sites/default/files/news_files/Response%20from%20Partnership%20to%20Amend%2042%20CFR%20Part%202.pdf.*

[10] *See* Published Comments—Request for Public Comment on the Confidentiality of Alcohol and Drug Abuse Patient Records, 79 FR 26929 (May 2014) Document 26, (June 23, 2014) at page 20, *https://www.samhsa.gov/sites/default/files/about_us/who_we_are/comments-100-120.pdf;* ''Privacy Laws are Hurting the Care of Patients with Addiction'' (July 2018*), https://www.statnews.com/2018/07/13/privacy-laws-patients-addiction/.*

[11] 42 U.S.C. 290dd–2(b)(1).

[12] 42 U.S.C. 290dd–2(b)(1)(B).

[13] 42 U.S.C. 290dd–2(b)(1)(D). Additionally, section 3221 of the CARES Act further emphasizes the patient's right to request restrictions on disclosures in both the Rules of Construction and the Sense of Congress. *See* CARES Act secs. 3221(j)(1) and (k)(2), respectively.

[14] 42 U.S.C. 290dd–2(c).

[15] 42 U.S.C. 290dd–2(f).

[16] CARES Act sec. 3221(g) added paragraph (i) to 42 U.S.C. 290dd–2 to insert an express prohibition against discrimination on the basis of information received pursuant to a disclosure of records. *See* 42 U.S.C. 290dd–2(i).

[17] 42 U.S.C. 290dd–2(j).

[18] 42 U.S.C. 290dd–2(k).

[19] CARES Act sec. 3221(i)(2).

court order, provided they first exercise reasonable diligence by attempting to determine if the targeted provider is a Part 2 program. The proposal would permit investigative agencies to seek a court order after obtaining records in such situations. An additional proposal would require agencies using this safe harbor to report annually to the Secretary.

Effective and Compliance Dates

The proposed effective date of a final rule would be 60 days after publication and the compliance date would be 22 months after the effective date. Entities subject to a final rule would have until the compliance date to establish and implement policies and practices to achieve compliance.

Part 2 does not contain a standard compliance period for changes to the regulations; however, the HIPAA Rules 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, except as otherwise provided (*e.g.,* in a specific rulemaking).[20] While the proposed rule would make only minor modifications to the Privacy Rule, the Department proposes to provide the same, substantial compliance period for both the proposed modifications to 45 CFR 164.520 and the more extensive Part 2 modifications. Accordingly, the Department would begin enforcement of the new and revised standards, in both regulations, 24 months after publication of a final rule. This 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 Privacy Rule.

The Department requests comment on whether the 22-month compliance period is an appropriate length of time for entities subject to a final rule to come into compliance and any benefits or unintended adverse consequences for entities or individuals of a shorter or longer compliance period.

Additionally, for the proposed accounting of disclosures requirements, the Department proposes to toll the compliance date for Part 2 programs until the effective date of a final rule on the HIPAA accounting of disclosures standard, 45 CFR 164.528. This would ensure that Part 2 programs do not incur new compliance obligations before covered entities and business associates under the Privacy Rule are obligated to comply.

Summary of Major Proposals

The Department proposes the following changes to 42 CFR part 2 that revise, delete, replace, or add sections to implement statutory requirements enacted pursuant to section 3221 of the CARES Act. The Department also proposes to amend 42 CFR part 2 to reflect applicable standards in the HIPAA Rules, reflect language used in the HIPAA Rules, align regulatory text with statutory spelling,[21] and improve clarity or readability. Additionally, the Department proposes to modify the NPP requirements in 45 CFR 164.520 consistent with section 3221(i) of the CARES Act.

This section summarizes major proposals in this NPRM. Additional proposed revisions are not listed here because they are not considered major.[22] All proposed changes are discussed in detail in section III of this NPRM:

1. § 2.1—Statutory authority for confidentiality of substance use disorder patient records.

Revise § 2.1 to more closely reflect the authority granted in 42 U.S.C. 290dd–2(g), especially with respect to court orders authorizing the disclosure of records.

2. § 2.2—Purpose and effect.

Amend paragraph (b) of § 2.2 to reflect that § 2.3(b) compels disclosures to the Secretary that are necessary for enforcement of this rule, using language adapted from the Privacy Rule at 45 CFR 164.502(a)(2)(ii). Add a new paragraph (b)(3) to this section to prohibit any limits on a patient's right to request restrictions on use of records for treatment, payment, or health care operations (TPO) or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the Privacy Rule.

3. § 2.3—Civil and criminal penalties for violations (proposed heading).

Amend the heading and replace title 18 U.S.C. enforcement with references to the HIPAA enforcement authorities in the Social Security Act at sections 1176 (civil enforcement, including the CMP tiers established by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009) and 1177 (criminal penalties),[23] as implemented in the Enforcement Rule.[24] Create a limitation on civil or criminal liability 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.[25]

4. § 2.4—Complaints of violations (proposed heading).

Amend the heading and insert requirements consistent with those applicable to HIPAA complaints under 45 CFR 164.530(d), (g), and (h), including: a requirement to establish a process for the Part 2 program to receive complaints, a prohibition against taking adverse action against patients who file complaints, and a prohibition against requiring individuals to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.

5. § 2.11—Definitions.

Add new terms and definitions to align with the following statutory and regulatory HIPAA terms: *Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Payment, Person, Public health authority, Treatment, Unsecured protected health information,* and *Use.* Create new defined terms *Intermediary, Investigative agency, and Unsecured record,* and modify the definitions of *Informant, Part 2 program director, Patient, Program, Records, Third-party payer, Treating provider relationship,* and *Qualified service organization.*

6. § 2.12—Applicability.

Replace ''Armed Forces'' with ''Uniformed Services'' in paragraph (c)(2) of § 2.12. Incorporate four

[20] *See* 45 CFR 160.105.

[21] 42 U.S.C. 290dd–2(b)(1)(B) provides in part that ''[a]ny information so disclosed may be redisclosed in accordance with the HIPAA regulations.'' To align with the statute's spelling of the term ''redisclosed'' and for drafting consistency, the Department proposes to modify the term ''re-disclosed'' (and related root words) to remove the hyphen, where appropriate, throughout this document. *See, e.g.,* proposed §§ 2.12(d)(2)(i)(C); 2.12(d)(2)(ii); 2.32(a)(1); 2.33(c); 2.34(b); 2.35(d); 2.52(b)(2); 2.53(a).

[22] Generally, the proposals not listed make wording changes, not substantive changes. These proposals are reviewable in the regulatory text 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 (proposed heading).

[23] *See* Public Law 111–5, 123 Stat. 226 (February 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) to add civil and criminal penalty tiers for violations of the HIPAA Administrative Simplification provisions.

[24] *See* 45 CFR part 160.

[25] 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.

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. Add language to qualify the term third-party payer with the phrase ''as defined in this part.'' Revise paragraph (e)(4)(i) to clarify when a diagnosis is not covered by Part 2.

7. § 2.13—Confidentiality restrictions and safeguards.

Redesignate § 2.13(d) requiring a list of disclosures as new § 2.24 and modify the text for clarity. Amend the heading to distinguish the right to a list of disclosures made by intermediaries from the proposed new right to an accounting of disclosures made by a Part 2 program.

8. § 2.14—Minor patients.

Change the verb ''judges'' to ''determines'' to describe a program director's evaluation and decision that a minor lacks decision making capacity.

9. § 2.15—Patients who lack capacity and deceased patients (proposed heading).

Replace outdated language, clarify 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, and add health plans to the list of entities to which a program may disclose records without consent.

10. § 2.16—Security for records and notification of breaches (proposed heading).

Apply the HITECH Act breach notification provisions [26] that are currently implemented in the Breach Notification Rule to breaches of records by Part 2 programs and retitle the provision to include breach notification to implement CARES Act provisions. Modify the provision to refer to the Privacy Rule de-identification standard at 45 CFR 164.514.

11. § 2.19—Disposition of records by discontinued programs.

Add 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), in order 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. Modernize the language to refer to ''non-electronic'' records and include ''paper'' records as an example of non-electronic records.

12. § 2.22—Notice to patients of federal confidentiality requirements.

Modify the Part 2 confidentiality notice requirements (hereinafter, ''Patient Notice'') to align with the NPP and address protections required by 42 U.S.C. 290dd–2, as amended by section 3221 of the CARES Act, for entities that create or maintain Part 2 records.

13. § 2.23—Patient access and restrictions on use and disclosure (proposed heading).

Add 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. § 2.24—Requirements for intermediaries (redesignated and proposed heading).

Retitle the redesignated section (to be moved from § 2.13(d)) as ''Requirements for intermediaries'' to clarify the responsibilities of recipients of records received under a consent with a general designation, such as health information exchanges, research institutions, accountable care organizations, and care management organizations.

15. § 2.25—Accounting of disclosures (proposed heading).

Add this 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 HITECH Act right to an accounting of certain disclosures of records for up to three years prior to the date the accounting is requested and add a right to an accounting of disclosures of records that mirrors the standard in the Privacy Rule at 45 CFR 164.528.

16. § 2.26—Right to request privacy protection for records (proposed heading).

Add this 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 HITECH Act rights implemented in the Privacy Rule at 45 CFR 164.522, namely: (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 (proposed heading).

Change the heading of subpart C to ''Uses and Disclosures With Patient Consent'' 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. § 2.31—Consent requirements.

Align the content requirements for Part 2 written consent with the content requirements for a valid HIPAA authorization and clarify how recipients may be designated in a consent to use and disclose Part 2 records for TPO.

19. § 2.32—Notice to accompany disclosure (proposed heading).

Change the heading of this section and align 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.

20. § 2.33—Uses and disclosures permitted with written consent (proposed heading).

To align 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, replace 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, until such time as the patient revokes the consent in writing. Create redisclosure permissions for two categories of recipients of Part 2 records pursuant to a written consent: (1) Permit a Part 2 program, covered entity, or business associate that receives Part 2 records pursuant to a written consent for TPO purposes to redisclose the records in any manner permitted by the Privacy Rule, except for certain proceedings against the patient; [27] and (2) Permit a lawful holder that is not a covered entity, business associate, or Part 2 program 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 in the consent.

21. § 2.35—Disclosures to elements of the criminal justice system which have referred patients.

For clarity, replace ''individuals'' with ''persons'' and clarify that permitted redisclosures of information are from Part 2 records.

22. Subpart D—Uses and Disclosures Without Patient Consent (proposed heading).

Change the heading of subpart D to ''Uses and Disclosures Without Patient Consent'' to reflect changes made to the

[26] 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.

[27] *See* 42 U.S.C. 290dd–2(b)(1)(B) and (2)(c).

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. § 2.51—Medical emergencies.

For clarity in § 2.51(c)(2), replace the term ''individual'' with the term ''person.''

24. § 2.52—Scientific research (proposed heading).

Revise the heading of § 2.52 to reflect statutory language. To further align Part 2 with the Privacy Rule, replace the requirements to render Part 2 data in research reports non identifiable with the Privacy Rule's de-identification standard in 45 CFR 164.514.

25. § 2.53—Management audits, financial audits, and program evaluation (proposed heading).

Revise the heading of § 2.53 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, add a provision to acknowledge the permission for use and disclosure of 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. § 2.54—Disclosures for public health (proposed heading).

Add a new § 2.54 to implement 42 U.S.C. 290dd–2(b)(2)(D), as amended by section 3221(c) of the CARES Act, to permit 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 (proposed heading).

Change the heading of subpart E 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. § 2.61—Legal effect of order.

Add the term ''use'' to clarify that the legal effect of a court order would include authorizing the use and disclosure of records, consistent with 42 U.S.C. 290dd–2(b) and (c), as amended by section 3221(e) of the CARES Act.

29. § 2.62—Order not applicable to records disclosed without consent to researchers, auditors, and evaluators.

For clarity, replace the term ''qualified personnel'' with a reference to the criteria that define such persons.

30. § 2.63—Confidential communications.

Revise paragraph (c) 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.

31. § 2.64—Procedures and criteria for orders authorizing uses and disclosures for noncriminal purposes (proposed heading).

Expand the types of forums where restrictions on use and disclosure of records in civil proceedings against patients apply [28] to expressly include administrative and legislative proceedings and also restrict the use of testimony conveying information in a record in civil proceedings against patients, absent consent or a court order. Add the term ''uses'' to the heading and in this section to align it with current statutory authority.

32. § 2.65—Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients (proposed heading).

Expand the types of forums where restrictions on uses and disclosure of records in criminal proceedings against patients apply [29] to expressly include administrative and legislative proceedings and also restrict the use of testimony conveying information in a Part 2 record in criminal proceedings against patients, absent consent or a court order.

33. § 2.66—Procedures and criteria for orders authorizing use and disclosure to investigate or prosecute a part 2 program or the person holding the records (proposed heading).

Create requirements for investigative agencies to follow in the event 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 before seeking a court order as required under § 2.66.

34. § 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.

Add new 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).

35. § 2.68—Report to the Secretary (proposed heading).

Create new requirements 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 and § 2.67.

36. 45 CFR 164.520—Notice of privacy practices for protected health information.

Revise 45 CFR 164.520 to implement updates to the NPP to address Part 2 confidentiality requirements, as required by section 3221(i)(2) of the CARES Act.

Background and Need for Proposed Rule

There are approximately 16,066 publicly funded SUD treatment facilities [30] and 1.8 million HIPAA covered entities and business associates, with an unknown percentage of entities subject to both HIPAA and Part 2. Part 2 records often also meet the definition of PHI when maintained by HIPAA covered entities (or their business associates on the covered entities' behalf). To ensure compliance with both sets of regulatory requirements, dually regulated entities subject to both Part 2 and the HIPAA Rules (*i.e.,* covered entities that also are Part 2 programs) must track and segregate the records that are subject to Part 2 from the records that are subject only to the HIPAA Rules and obtain specific written consent for most uses and disclosures of Part 2 records (including uses and disclosures for non-emergency treatment purposes). The Department has been urged by many stakeholders to change Part 2 to eliminate the need for data segmentation.[31]

[28] *See* 42 CFR part 2, subpart E.

[29] *Id.*

[30] *See* Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N–SSATS): 2020. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021, *https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.*

[31] 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 federally qualified health centers and other integrated settings in which SUD treatment may be provided. *See also* public comments expressed and summarized in 85 FR 42986, *https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-*

The preamble to the 2000 Final Privacy Rule explained how entities subject to the Privacy Rule and Part 2 could comply with both rules because in most cases the rules do not conflict. The Privacy Rule permits, but does not require, some disclosures that are not permitted by Part 2. Complying with Part 2's prohibitions on such disclosures would not be a violation of the Privacy Rule. And in instances where Part 2 permits disclosures that would otherwise be restricted by the Privacy Rule, an entity that is subject to both sets of regulations would be able to comply with the Privacy Rule's restrictions without violating Part 2.[32]

Although the Department intended to facilitate compliance by entities subject to both regulatory schemes, significant differences in the statutorily permitted uses and disclosures of Part 2 records and PHI contributed to ongoing operational compliance challenges. For example, once a HIPAA covered entity or business associate disclosed PHI to a person who was not a covered entity or business associate, the information was no longer protected by the Privacy Rule, and thus the Privacy Rule's limitations on uses and disclosures did not apply. In contrast, Part 2 strictly limited the redisclosure of Part 2 records by any individual or entity that received a Part 2 record directly from a Part 2 program or other ''lawful holder'' of patient identifying information, absent written patient consent or as otherwise permitted under the regulations.[33] [34]

Regarding Part 2 records, a treating provider that is not a Part 2 program could record information about the treatment of an individual's SUD in its non-Part 2 records, even if it gleaned the information from a Part 2 record, and the information in the non-Part 2 records would not be subject to Part 2; however, any Part 2 records received from a Part 2 program or other lawful holder would need to be segregated or segmented.[35] Previously, the need to segment Part 2 records from other health records created data ''silos'' that hampered the integration of SUD treatment records into covered entities' electronic record systems and billing processes. Some lawmakers have argued that these silos perpetuated negative stereotypes about persons with SUD and inhibited coordination of care [36] [37] during the opioid epidemic.[38] In 2019, the National Association of Attorneys General (NAAG) urged Congress to update the 40-year-old Part 2 regulation that was created in a time of ''intense stigma'' surrounding SUD treatment because it now serves to ''perpetuate that stigma, as the principle underlying these rules is that [SUD] treatment is shameful and records of it should be withheld from other treatment providers in ways that we do not withhold records of treatment of other chronic diseases.'' [39] In that same year ''nearly 50,000 people in the United States died from opioid-involved overdoses.'' [40] During a congressional hearing, ''The Opioid Crisis: The Role of Technology and Data in Preventing and Treating Addiction,'' Senator Patty Murray (D–WA) observed that, ''[t]echnology and data offer important opportunities to address the opioid crisis, to prevent addi[c]tion, and avoid the tragedy so many families are facing.'' [41]

To address these concerns, Congress enacted the CARES Act, which requires the Department to promulgate regulations modifying the confidentiality requirements for Part 2 records.[42] This rulemaking proposes modifications to 42 CFR part 2 and the Privacy Rule that are necessary to implement the statutory amendments made to 42 U.S.C. 290dd–2, and additional modifications to Part 2 to better align certain provisions of Part 2 to the Privacy Rule and address concerns about potential liability for government agencies in the course of investigating and prosecuting Part 2 programs under the new penalties and enforcement scheme.

A. Statutory and Regulatory Background

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.[43] The 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 1972 [44] 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

disorder-patient-records; and see *https://aahd.us/wp-content/uploads/2021/01/PartnershipRecommendationsforNextPart2-uleLtrtoNomineeBecerra_01082021.pdf.*

[32] *See* 65 FR 82482 (December 28, 2000).

[33] *See* 42 CFR 2.12(d)(2)(i)(C).

[34] *See* 42 CFR 2.11, definitions of ''Patient identifying information'' and ''Disclose''.

[35] *See* 42 CFR 2.12(d)(2)(ii).

[36] *See, e.g.,* remarks of U.S. Representative Earl Blumenauer: ''If substance use disorder treatment is not included in your entire medical records, then they are not complete. It makes care coordination more difficult and can lead to devastating outcomes. This bill works to remove the stigma that comes with substance use disorders and ensures necessary information is available for safe, efficient, and transparent treatment for all patients.'' *See* also remarks of U.S. Representative Markwayne Mullin: ''It's time that we stop stigmatizing those struggling with opioid abuse and give physicians the tools they need to help their patients. Mental health and physical health have been treated in a silo for too long. Our bill breaks down those barriers so the doctor can treat the whole patient. I'm proud to introduce this bill with my colleagues so that we can provide 21st century care to those who need it the most'', *https://blumenauer.house.gov/media-center/press-releases/blumenauer-and-mullin-introduce-bipartisan-legislation-address-opioid.*

[37] *But see* 85 FR 42986 (July 15, 2020), in which the Department finalized a rule permitting the disclosure of Part 2 records for care coordination by certain ''lawful holders'' that receive a record for payment or health care operation activities directly from a Part 2 program or other lawful holder.

[38] In 2017, the Department declared a public health emergency related to the opioid crisis. *See* Public Health Emergency (October 26, 2017), *https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf. https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx.*

[39] NAAG Requests Removal of Federal Barriers to Treat Opioid Use Disorder (August 5, 2019), at *https://www.naag.org/policy-letter/naag-requests-removal-of-federal-barriers-to-treat-opioid-use-disorder/.*

[40] Opioid Overdose Crisis, National Institutes of Health National Institute on Drug Abuse (March 11, 2021), *https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis. See also* CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2019, *https://wonder.cdc.gov.*

[41] Hearing of the Committee on Health, Education, Labor, and Pensions United States Senate, ''The Role of Technology and Data in Preventing and Treating Addiction.'' (February 27, 2018), *https://www.govinfo.gov/content/pkg/CHRG-115shrg28855/pdf/CHRG-115shrg28855.pdf.*

[42] *See* sec. 3221(i) of the CARES Act.

[43] *See* sec. 333, Public Law 91–616, 84 Stat. 1853 (December 31, 1970) (codified at 42 U.S.C. 2688h).

[44] *See* sec. 408, Public Law 92–255, 86 Stat. 65 (March 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.

order granted after application showing good cause.[45]

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 [46] expanded the types of records protected by confidentiality restrictions to include records relating to alcoholism, alcohol abuse, and drug abuse prevention, maintained in connection with any program or activity conducted, 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.[47]

In 1992, section 131 of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (ADAMHA Reorganization Act) [48] added section 543, Confidentiality of Records, to the Public Health Service Act (PHSA) (codified at 42 U.S.C. 290dd–2) (''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) [49] to ''the need to avert a substantial risk of death or serious bodily harm.'' [50] Congress also established criminal penalties for Part 2 violations under title 18 of the United States Code, Crimes and Criminal Procedure.[51] Finally, section 543 granted broad authority to the Secretary 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.'' [52]

In 1975, the Department, promulgated the first federal regulations implementing statutory SUD confidentiality provisions at 42 CFR part 2.[53] 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.[54] After the 1992 enactment of the ADAMHA Reorganization Act (Pub. L. 102–321), 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 only those entities or units within a general medical facility that hold themselves out as providing diagnosis, treatment, or referral for treatment, or specialized personnel (who are identified as providing such services as a primary function) and which directly or indirectly receive federal assistance.[55]

HIPAA and the HITECH Act

In 1996, Congress enacted HIPAA,[56] which included Administrative Simplification provisions requiring the establishment of national standards [57] to protect the privacy and security of individuals' health information and establishing civil money and criminal penalties for violations of the requirements, among other provisions.[58] 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.[59] Certain provisions of the HIPAA Rules also apply directly to business associates of covered entities.[60]

The Privacy Rule, including provisions implemented as a result of the HITECH Act,[61] 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 otherwise permitted by the Privacy Rule.[62] The 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; [63] to public health authorities for public health purposes; [64] and for research in the form of a limited data set [65] or pursuant to a waiver of authorization by a Privacy Board or Institutional Review Board.[66] The 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

[45] *Id.*

[46] See sec. 101, title I, Public Law 93–282, 88 Stat. 126 (May 14, 1974), 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''.

[47] *See* sec. 408, title I, Public Law 92–255, 86 Stat. 79 (March 21, 1972) (originally codified at 21 U.S.C. 1175). *See* 21 U.S.C. 1175 note for complete statutory history.

[48] *See* sec. 131, Public Law 102–321, 106 Stat. 323 (July 10, 1992) (codified at 42 U.S.C. 201 note).

[49] *See* sec. 333, Public Law 91–616, 84 Stat. 1853 (December 31, 1970).

[50] *See* sec. 131, Public Law 102–321, 106 Stat. 323 (July 10, 1992) (codified at 42 U.S.C. 201 note).

[51] *Id.,* adding sec. 543(b)(2)(C) to the PHSA.

[52] *Id.,* adding sec. 543(g) to the PHSA.

[53] *See* 40 FR 27802 (July 1, 1975).

[54] *See* 52 FR 21796 (June 9, 1987). *See also* Notice of Decision to Develop Regulations, 45 FR 53 (January 2, 1980) and 48 FR 38758 (August 25, 1983).

[55] *See* 60 FR 22296 (May 5, 1995). *See also* 59 FR 42561 (August 18, 1994) and 59 FR 45063 (August 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.

[56] *See* Public Law 104–191, 110 Stat. 1936 (August 21, 1996).

[57] Cited at fn. 3. *See also* sec. 264 of HIPAA (codified at 42 U.S.C. 1320d–2 note).

[58] *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.

[59] *See* 42 U.S.C. 1320d–1 (applying Administrative Simplification provisions to covered entities).

[60] *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 Rules that apply directly to business associates (available at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html*).

[61] The HITECH Act extended the applicability of certain Privacy Rule requirements and all of the 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 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 EHR, to receive an accounting of disclosures of their PHI with respect to 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.).

[62] *See* 45 CFR 164.502(a).

[63] *See* 45 CFR 164.506.

[64] *See* 45 CFR 164.512(b).

[65] *See* 45 CFR 164.514(e)(1–4).

[66] *See* 45 CFR 164.512(i).

practices; to request restrictions of certain uses and disclosures; to access (*i.e.,* to inspect and obtain a copy of) their PHI; to request an amendment of their PHI; and to receive an accounting of certain disclosures of their PHI.[67] Finally, the Privacy Rule specifies standards for de-identification of PHI such that, when applied, the information is no longer individually identifiable health information and subject to the HIPAA Rules.[68]

The 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; [69] protect against reasonably anticipated threats or hazards to the security or integrity of the information [70] and reasonably anticipated impermissible uses or disclosures; [71] and ensure compliance by their workforce.[72]

The Breach Notification Rule, codified at 45 CFR parts 160 and 164, subparts A and D, implements HITECH Act requirements [73] for covered entities to provide notification to affected individuals, the Secretary, and in some cases the media, following a breach of unsecured PHI. The 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, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of ''unsecured'' PHI, subject to three exceptions: [74] (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 (OHCA) 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 have been able to retain the information.

The 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.[75]

The 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 Rules, compliance reviews, the imposition of (CMPs), and procedures for hearings. The 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.[76] However, the Enforcement Rule also provides for informal resolution of potential noncompliance,[77] which occurs through voluntary compliance by the regulated entity, corrective action, or a resolution agreement with the payment of a settlement amount to OCR.

The Department promulgated or modified key provisions of the HIPAA Rules as part of the 2013 Omnibus Final Rule, 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 entities' level of culpability.[78] The Secretary of HHS delegated authority to OCR to make decisions regarding the implementation and interpretation of the Privacy, Security, Breach Notification, and Enforcement Rules.[79] [80]

Earlier Efforts To Align Part 2 With the HIPAA Rules

Prior to amendment by the CARES Act, section 290dd–2 provided that records could be disclosed only with the patient's specific written consent for each disclosure, with limited exceptions.[81] 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.[82] 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 implementing regulations require specific patient consent for most uses and disclosures of Part 2 records, including for non-emergency treatment purposes. In contrast, the Privacy Rule permits covered entities to use and disclose an individual's PHI for TPO without the individual's valid HIPAA authorization.[83]

The Department has modified and clarified Part 2 several times to align certain provisions more closely with the Privacy Rule,[84] address changes in health information technology, 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.[85] For example, 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 Privacy Rule at

[67] *See* 45 CFR 164.520, 164.522, 164.524, 164.526 and 164.528.

[68] *See* 45 CFR 164.514(a–c).

[69] *See* 45 CFR 164.306(a)(1).

[70] *See* 45 CFR 164.306(a)(2).

[71] *See* 45 CFR 164.306(a)(3).

[72] *See* 45 CFR 164.306(a)(4).

[73] *See* sec. 13402 of the HITECH Act (codified at 42 U.S.C. 17932).

[74] *See* 45 CFR 164.402 para. (1).

[75] *Ibid.* para. (2).

[76] Criminal penalties may be imposed by the Department of Justice for certain violations under 42 U.S.C. 1320d–6.

[77] *See* 45 CFR 160.304. *See also* 45 CFR 160.416 and 160.514.

[78] *See* 78 FR 5566 (January 25, 2013).

[79] *See* Office for Civil Rights; Statement of Delegation of Authority, 65 FR 82381 (December 28, 2000); Office for Civil Rights; Delegation of Authority, 74 FR 38630 (August 4, 2009); Statement of Organization, Functions and Delegations of Authority, 81 FR 95622 (December 28, 2016).

[80] *See* 65 FR 82381 (December 28, 2000).

[81] The limited exceptions are codified in current regulation at 42 CFR 2.12(c), 42 CFR part 2 subpart D, and 42 CFR 2.33(b).

[82] *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.

[83] *See* 45 CFR 164.501.

[84] *See* 85 FR 42986 and 83 FR 239 (January 3, 2018).

[85] 82 FR 6052 (January 18, 2017). *See also* 81 FR 6988 (February 9, 2016).

45 CFR 164.514(b)(2)(i) for those identifiers that are not already listed in the Part 2 definition.[86]

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 necessarily definitive so as to be included in regulatory text.[87] The Department also acknowledged the similarity of the list of activities to those included in the Privacy Rule definition of ''health care operations'' but declined to fully incorporate that definition into Part 2.[88] The Department specifically excluded care coordination and case management from the list of payment and health care operations activities permitted without patient consent under Part 2 based on a determination that these activities are akin to treatment. The Department also codified in regulatory text language for an abbreviated notice to accompany disclosure of Part 2 records.[89] Although the rule retained the requirement that a patient must consent before a lawful holder may redisclose Part 2 records for treatment,[90] the Department explained that the purpose of the Part 2 regulations is to ensure that a patient is not made more vulnerable by reason of the availability of a treatment record than an individual with a SUD who chooses not to seek treatment. 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.[91]

In a final rule published July 15, 2020,[92] 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.[93] 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 Privacy Rule definition of health care operations, including care coordination and case management activities, into paragraph (k)(4) of 42 U.S.C. 290dd–2.[94] The July 2020 final rule also modified the consent requirements in § 2.31 by establishing special requirements for written consent [95] when the recipient of Part 2 records is a health information exchange (HIE) (as defined in 45 CFR 171.102 [96]). In this NPRM, the Department now proposes a definition for the term ''intermediary'' [97] to further facilitate the exchange of Part 2 records in new models of care, including those involving an HIE, a research institution providing treatment, an accountable care organization, or a care management organization.

The Department again modified Part 2 on December 14, 2020,[98] 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 Act [99] 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 HIPAA and HITECH Act privacy use and disclosure standards, breach notification standards, and enforcement authorities that apply to PHI, among other modifications.

The requirements in sections 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 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 violations, respectively. Section 3221 also amended 42 U.S.C. 290dd–2j) and (k) by adding HITECH Act breach notification requirements and new terms and definitions consistent with the HIPAA Rules and the HITECH Act, respectively. Finally, section 3221 requires the Department to modify the NPP [100] 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 patients' 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 PHSA [101] 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

[86] *See* 82 FR 6052, 6064.

[87] *See* 83 FR 239, 241–242.

[88] *Id.* at 242.

[89] 83 FR 239 (January 3, 2018). *See also* 82 FR 5485 (January 18, 2017).

[90] *Id.* at 242.

[91] *Id.*

[92] 85 FR 42986. *See also* 84 FR 44568.

[93] *See* 42 CFR 2.33(b).

[94] *See* 85 FR 42986, 43008–009. Sec. 3221(k)(4) expressed the Sense of Congress that the Department should exclude clause (v) of paragraph 6 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.

[95] *See* 85 FR 42986, 43006.

[96] *See* 85 FR 42986, 43006, *See also* 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 FR 25642 (May 1, 2020).

[97] *See* proposed 42 CFR 2.11, Definitions: *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 participants for the treatment of the patient—*e.g.,* a health information exchange, a research institution that is providing treatment, an accountable care organization, or a care management organization.

[98] 85 FR 80626 (December 14, 2020).

[99] Public Law 116–136, 134 Stat. 281 (March 27, 2020). Significant components of section 3221 are codified at 42 U.S.C. 290dd–2 as further detailed in this NPRM.

[100] Section 3221(i) requires the Secretary to update 45 CFR 164.520, the Privacy Rule requirements with respect to the NPP.

[101] Paragraph (1) is codified at 42 U.S.C. 290dd–2(b).

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 this section for the purposes of treatment, payment, and health care operations 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 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 that this means that the entity receiving the records based on such general consent, and then redisclosing the records, must be a covered entity, business associate, or Part 2 program. The Department's proposals throughout this NPRM 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 or maintenance of social services and benefits provided or funded by Federal, State, or local governments.[102] Further, the new paragraph (i)(2) prohibits discrimination by any recipient of Federal funds against individuals based on their Part 2 records.[103] As a recent legal analysis noted, ''The decision to protect individuals whose disclosed patient records reveal or appear to reveal current illegal use of drugs is also consistent with Section 3221's specific purpose to remove well-founded fear of discrimination as a barrier to treatment.'' [104] Patients with SUD who are currently using illegal drugs are not protected from discrimination on the basis of their illegal drug use under existing law of the Rehabilitation Act of 1973,[105] Americans with Disabilities Act (ADA),[106] the Affordable Care Act,[107] and the Fair Housing Act.[108] The CARES Act nondiscrimination provision, in conjunction with the newly applicable HITECH Act penalty tiers, will serve to protect the treatment records of all patients with SUD, whether or not they are currently using illicit drugs. The Department intends to implement the CARES Act antidiscrimination provisions in a separate rulemaking.

Section-by-Section Description of Proposed Amendments to 42 CFR Part 2

Below, the Department describes the proposals in this NPRM to amend 42 CFR part 2 and 45 CFR 164.520 to implement changes made to 42 U.S.C. 290dd–2, as amended by section 3221 of the CARES Act. Some of the Department's proposals are not expressly required by the CARES Act, but are proposed to align the language of this part with that in the Privacy Rule and to clarify already-existing Part 2 permissions or restrictions. The Department believes these additional proposals fall within the Department's scope of regulatory authority and are necessary to facilitate implementation of the CARES Act. For example, consistently throughout this NPRM, the Department proposes to re-order the terms ''disclosure and use'' to ''use and disclosure'' [109] to better align the language of Part 2 with the Privacy Rule which generally regulates the ''use and disclosure'' of PHI.[110] The Department does not believe these proposed changes are substantive, but requests comment on this assumption. In another example, the Department proposes to add the term ''use'' to where only the term ''disclose'' exists in regulatory text, or in some cases to add the term ''disclose'' to an existing ''use'' because it more accurately describes the scope of the activity that is the subject of the regulatory provision or could be within the scope of the activity. These changes are aligned with changes made to 42 U.S.C. 290dd–2 paragraph (b)(1)(A) 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) 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 programs in accordance with the HIPAA Rules for TPO purposes); and to paragraph 42 U.S.C. 290dd–2(c) by section 3221(e) of the CARES Act (prohibiting disclosure and use of Part 2 records in proceedings against the patient). The Department describes these proposed additions of terms in each section of this NPRM where applicable.[111] The Department requests

[102] *See* sec. 3221(g) of the CARES Act.

[103] *Id.*

[104] *See* Dineen, Kelly K., & Pendo, Elizabeth, ''Substance Use Disorder Discrimination and the CARES Act: Using Disability Law to Inform Part 2 Rulemaking'' (February 2, 2021) (available at *https://arizonastatelawjournal.org/wp-content/uploads/2021/02/02-Dineen-_-Pendo.pdf*) and Johnson, Kimberly, ''COVID–19: Isolating the Problems in Privacy Protection for Individuals with Substance Use Disorder'' (May 1, 2021) (available at *https://ssrn.com/abstract=3837955*). *See also* remarks of U.S. Representative Michael C. Burgess: ''Current [P]art 2 law does not protect individuals from discrimination based on their treatment records and, to this date, there have been no criminal actions undertaken to enforce [P]art 2.'' (available at *https://www.congress.gov/congressional-record/2018/06/20/house-section/article/H5325-1*).

[105] *See* sec. 504, Public Law 93–112, 86 Stat. 355 (September 26, 1973) (codified at 29 U.S.C. 701, 705).

[106] *See* Public Law 101–336, 104 Stat. 327 (July 26, 1990) (codified at 42 U.S.C. 12101, 12210).

[107] *See* sec. 1557, Public Law 111–148, 124 Stat. 119 (March 23, 2010) (codified at 42 U.S.C. 18001, 18116).

[108] *See* sec. 3601–19, Public Law 90–284, 82 Stat. 81 (April 11, 1968) (codified at 42 U.S.C. 3601, 3602).

[109] *See e.g.,* proposed regulatory text at §§ 2.2(a)(2), (a)(3), and (b)(1), Purpose and effect; 2.12(c)(5) and (c)(6), Applicability; 2.13(a) and (b), Confidentiality restrictions and safeguards; 2.21(b), Relationship to federal statutes protecting research subjects against compulsory disclosure of their identity; 2.34(b), Disclosures to prevent multiple enrollments; 2.35(d), Disclosures to elements of the criminal justice system which have referred patients; 2.53(a), (b)(1)(iii), (e)(1)(iii), (e)(6), (f), Management audits, financial audits, and program evaluation (proposed heading); subpart E, Court Orders Authorizing Use and Disclosure (proposed heading); 2.61(a), Legal effect of order; 2.62, Order not applicable to records disclosed without consent to researchers, auditors and evaluators; 2.65 heading, 2.65(a) and (d), 2.65(e), (e)(1), and (e)(3), Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients (proposed heading); 2.66 heading, 2.66(a)(1) and 2.66(d), 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 heading).

[110] Consistently, the Department refers to ''uses and disclosures'' or ''use and disclosure'' in the Privacy Rule. *See, e.g.,* 45 CFR 164.502 Uses and disclosures of protected health information: General rules.

[111] *See, e.g.,* proposed §§ 2.12(a)(1), (c)(3) and (c)(4), (d)(2), and (e)(3), Applicability; 2.13(a), Confidentiality restrictions and safeguards; 2.14(a) and (b), Minor patients; 2.15(a)(2), (b)(1) and (b)(2), Patients who lack capacity and deceased patients; 2.20, Relationship to state laws; *2*.23 Patient access and restrictions on use and disclosure (proposed heading) and 2.33(b); Subpart C—Uses and Disclosures With Patient Consent (proposed heading); 2.31(a), (a)(1) and (2), (a)(4)(ii)(B), (a)(10), and (a)(10)(i) and (ii), Consent requirements; 2.33 Uses and disclosures permitted with written consent (proposed heading), and paragraphs 2.33(a), (b), (b)(1), and (b)(2); Subpart D—Uses and Disclosures Without Patient Consent (proposed heading); 2.53(e)(5), Management audits, financial audits, and program evaluation 2.61(a) and (b)(1)

Continued

comment on its proposals to reorder the terms ''use'' and ''disclosure'' as described, and to add the term ''use'' to clarify these regulations as described above.

In addition, the Department proposes changes to subpart E, *Court Orders Authorizing Use and Disclosure,* relying on both the Secretary's broad rulemaking authority under section 543 of the PHSA and on the authority granted in section 3221 of the CARES Act. The Department proposes to heighten protections against use or disclosure of records in proceedings against patients by aligning the regulatory language regarding the scope of proceedings to which subpart E applies with the amended statute to expressly include administrative and legislative proceedings [112] and to expressly include testimony that relays information contained in records.[113] Additionally, the Department is adopting the HIPAA phrasing of ''use and disclosure'' in most instances where only one of those terms is used in the current regulation, including throughout subpart E.

The Department also proposes additional changes to facilitate compliance by investigative agencies when they seek records for investigations and prosecutions of Part 2 programs pursuant to applicable authorities. In particular, the Department proposes to limit liability for violations when an investigative agency unknowingly receives Part 2 records in the course of investigating a Part 2 program or person holding Part 2 records, provided the agency takes certain actions, and to require annual reporting to the Secretary by investigative agencies about the use of the proposed safe harbor. The Department is proposing these changes because the Department believes the proposals are a necessary consequence of the new enforcement penalties for violations of Part 2 [114] pursuant to 42 U.S.C. 290dd–2(f) as amended by section 3221 (f) and the expanded scope of proceedings where a court order is required [115] pursuant to 42 U.S.C. 290dd–2(c) as amended by section 3221(e). In particular, the Department understands that investigative agencies could potentially become subject to the new penalties for violations in the event that they are unaware that a provider under investigation is subject to Part 2 and as a result they fail to follow the requirements of subpart E before obtaining the provider's records. The Department requests comment on these additional proposed changes.

The Department further requests comment on all proposals described in the following paragraphs of this NPRM, including those expressly implementing CARES Act amendments to section 290dd–2, those the Department describes as necessary to further align this part with the Privacy Rule, and those proposals described as necessary to clarify the full scope of activities that it is regulating in this part. The Department also requests comment on all aspects of the Regulatory Impact Analysis, including the assumptions and estimates about the costs and benefits of the proposed changes, and the alternatives the Department considered when developing the proposals in this NPRM. The Department proposes the following amendments to this part:

A. § 2.1—Statutory Authority for Confidentiality of Substance Use Disorder Patient Records

The Department proposes to revise § 2.1 to more closely align this section with the statutory text of 42 U.S.C. 290dd–2(g) and add references to subsection 290dd–2(b)(2)(C) related to the issuance of court orders authorizing disclosures of Part 2 records.

§ 2.2—Purpose and Effect

Section 2.2 of 42 CFR part 2 establishes the purpose and effect of regulations imposed in this part upon the use and disclosure of Part 2 records. The Department proposes to add language to paragraph (b) of § 2.2 to conform that paragraph to changes proposed to § 2.3(b) that would compel disclosures to the Secretary that are necessary for enforcement of this rule. The new language is adapted from a similar provision of the Privacy Rule at 45 CFR 164.502(a)(2)(ii).

The Department also proposes to replace the phrase ''disclosure and use'' by re-ordering the phrase to ''use or disclosure'' at §§ 2.2(a), (a)(4), and 2.2(b)(1), to align the language with that used in the Privacy Rule.

The Department proposes several changes in § 2.2 that would facilitate implementation of the CARES Act in general. For example, in §§ 2.2(a)(2), (a)(3), and (b)(1), the Department proposes to add the phrase ''uses and'' in front of the existing term ''disclose'' or ''disclosures.'' The Department proposes these additions in §§ 2.2(a)(2) and (3), which list subparts C and D of this part, to conform to changes the Department proposes to the heading titles of subparts C and D. In those heading titles, the Department proposes to refer to ''Uses and Disclosures with Patient Consent'' and ''Uses and Disclosures without Patient Consent'' respectively.

In § 2.2(b)(1), Effect, the Department proposes to refer to ''use and disclosure'' instead of only ''disclosure'' to better describe how the regulations in this part, as modified by the CARES Act, prohibit the ''use and disclosure'' of Part 2 records. The Department proposes to modify the end of § 2.2(b)(1) to provide that the regulations generally do not generally require the use or disclosure of Part 2 records under any circumstance except when disclosure is required by the Secretary to investigate or determine a person's compliance with this part pursuant to § 2.3(b), now proposed for modification to reflect newly required civil and criminal penalties for violations of this part.

Finally, the Department proposes to add a new paragraph (b)(3) to § 2.2 to incorporate the rules of construction in section 3221(j)(1) and (2) of the CARES Act. Accordingly, the proposed paragraphs would 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 Privacy Rule.

In addition to the above-described proposed amendments to § 2.2, the Department proposes minor wording changes to improve readability or conform the use of terms to newly proposed definitions. These proposals are reflected in proposed regulatory text and may be reflected throughout this NPRM and include:

- Inserting a parenthetical reference to ''records'' to reflect how the Department proposes to refer to SUD records; and
- Striking the word ''patient'' from in front of the term ''record''.

The Department requests comments on all proposed changes to this section.

and (b)(2), Legal Effect of order; 2.64 heading, Procedures and criteria for orders authorizing uses and disclosures for non-criminal purposes (proposed heading), and paragraphs (a) and (e); 2.65(a) Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients (proposed heading); 2.67 (d)(3), 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.

[112] *See* proposed §§ 2.63, 2.64, 2.65.

[113] *See* proposed §§ 2.64. 2.65, 2.66.

[114] *See* proposed § 2.3.

[115] *E.g.,* Expressly including legislative and administrative proceedings and testimony relaying information contained in records, as discussed above.

§ 2.3—Civil and Criminal Penalties for Violations (Proposed Heading)

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. As amended by section 3221(f) of the CARES Act, 42 U.S.C. 290dd–2(f) applies the provisions of §§ 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. Therefore, the Department proposes to replace title 18 criminal enforcement with civil and criminal penalties under §§ 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6), respectively, as implemented in the Enforcement Rule.

Specifically, the Department proposes to rename § 2.3 as *Civil and criminal penalties for violations* and reorganize § 2.3 into section paragraphs 2.3(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 §§ 1176 and 1177 of the Social Security Act, respectively, to violations of Part 2.

After consultation with the Department of Justice, the Department proposes in § 2.3(b) to create a limitation on civil or criminal liability 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, they may unknowingly receive Part 2 records without first obtaining the requisite court order, provided that specified conditions are met. Such a safe harbor, as proposed, would be limited to only instances where records are obtained for the purposes of investigating a program or person holding the record, not a patient. Investigative agencies are required to follow Part 2 requirements for obtaining, using, and disclosing Part 2 records as part of an investigation or prosecution; such requirements include 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. Investigative agencies' potential liability for violating Part 2 has increased due to the expanded application of HIPAA/HITECH Act penalties for violations, codified at 42 U.S.C. 1320d–5 (CMPs) and 1320d–6 (criminal penalties), to violations of Part 2. In addition, the need for investigation and prosecution of bad actors has increased in accordance with the intensity and duration of the opioid overdose epidemic.[116] The Department solicits comments on the need for investigation of Part 2 programs and holders of Part 2 records and a related safe harbor for law enforcement due to proposed changes in enforcement of Part 2 requirements.

To address concerns about potential liability for Part 2 violations arising from investigators who, in good faith, unknowingly receive Part 2 records, the Department proposes at § 2.3(b) to create a limitation on civil or criminal liability for persons acting on behalf of investigative agencies if they unknowingly receive Part 2 records without first obtaining the required court order while investigating or prosecuting a Part 2 program or other person holding Part 2 records (or their employees or agents). The limitation on liability would be available for uses or disclosures inconsistent with Part 2 when the person acted with reasonable diligence to determine in advance whether Part 2 applied to the records or program. Paragraph (b)(1) would also clarify what constitutes ''reasonable diligence'' in determining whether Part 2 applies to a record or program before an investigative agency makes an investigative demand or places an undercover agent with the program or person holding the records. Reasonable diligence 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. 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 by:

(1) checking a prescription drug monitoring program 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) would require an investigative agency to meet any other applicable requirements within Part 2 for any use or disclosure of the records that occurred, or will occur, after the investigative agency knew, or by exercising reasonable diligence would have known, that it received Part 2 records. The Department has added applicable requirements in § 2.66 and § 2.67, discussed below, and requests comment on the impact of the proposed safe harbor on patient privacy and access to SUD treatment.

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. The current rule contains no mechanism for an investigative agency to correct an error if it unknowingly obtains Part 2 records and as a result fails to obtain the required court order in advance. By proposing a pathway for investigative agencies to seek the required court order after the fact (a pathway that is only available for agencies that have first exercised reasonable diligence to determine in advance whether Part 2 applies), the proposal creates an incentive for investigative agencies to take steps that should reduce the need for ''after the fact'' court orders. Thus, investigative agencies that follow the proposed reasonable diligence steps and yet unknowingly receive Part 2 records and then seek a court order would be less likely to be denied on the basis of a procedural shortcoming and would not risk incurring HIPAA/HITECH Act penalties. Investigative agencies that do not use reasonable diligence as proposed at § 2.3(b)(1) 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 that proposed § 2.3(b) may be viewed as a reduction in privacy protection, but believes that the exclusive application to investigations and prosecution of programs and holders of records affords an overall benefit without harming patient confidentiality when the proposed additional protections in §§ 2.66 and 2.67 are applied.[117] The Department has limited the proposed safe harbor to investigative agencies that unknowingly obtain Part 2 records and relies on the CMP tiers to allow appropriate flexibility when a Part 2 program has unknowingly violated Part 2. However, the Department solicits comments on situations for which a safe harbor should be considered for SUD providers that unknowingly hold Part 2 records and unknowingly disclose them

[116] *See Opioid Enforcement Effort,* Department of Justice, Consumer Protection Branch, *https://www.justice.gov/civil/consumer-protection-branch/opioid* and *Understanding the Epidemic,* Centers for Disease Prevention and Control, *https://www.cdc.gov/drugoverdose/epidemic/index.html.*

[117] For example, using ''John Doe'' in the application for a court order and keeping records that contain patient identifying information under seal.

in violation of Part 2. As mentioned above, the Department also solicits comments on the impact of this proposed safe harbor to patient privacy and access to SUD treatment.

The Department does not intend to modify the applicability of § 2.12 or § 2.53 for investigative agencies, but to make the proposed safe harbor available in those situations where a court order would otherwise be required for a government agency to use or disclose records under these regulations. Thus, under § 2.12(c) an agency with direct administrative control over a Part 2 program still would not be subject to the Part 2 limits on communications between the program and the agency for purposes of diagnosis, treatment, or referral of patients, although the agency is also an investigative agency due to its supervisory role. Similarly, 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).

Proposed § 2.3(c) would specify that the Enforcement Rule [118] 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.[119] The Department requests comment on the likely benefits and costs of these proposed changes.

§ 2.4—Complaints of Violations (Proposed Heading)

Paragraphs (a) and (b) of this section currently 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 opioid treatment program may be directed to the U.S. Attorney and also to the Substance Abuse and Mental Health Services Administration (SAMHSA). Section 290dd–2(f), 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 1176 of the Social Security Act in accordance with the Enforcement Rule. To implement the change from U.S. Attorney enforcement, the Department proposes to re-title the heading to this section, replacing ''Reports of violations'' with ''Complaints of violations,'' 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 filing complaints of potential violations with a Part 2 program or the Secretary. The Department notes that SAMHSA continues to regulate opioid treatment programs (OTPs) and may receive reports of alleged violations by OTPs of federal opioid treatment standards, including privacy and confidentiality *requirements.*

Specifically, the Department proposes to add § 2.4(a) to require a Part 2 program to have a process to receive complaints concerning the program's compliance with the Part 2 regulations. Proposed § 2.4(b) would provide that a 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 proposes to add § 2.4(c) to prohibit a 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.

The proposed changes to § 2.4 would align Part 2 with 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(b) would align with the Privacy Rule provision at 45 CFR 164.530(g), *Standard: Refraining from intimidating or retaliatory acts.* The proposed § 2.4(c) would be consistent with the 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.

The Department requests comment on these proposed changes, including any concerns about potential unintended negative consequences on programs or patients of aligning § 2.4 with the cited provisions of the Privacy Rule.

§ 2.11—Definitions

Section 2.11 includes definitions for key regulatory terms in 42 CFR part 2. The Department proposes to add thirteen defined regulatory terms and modify the definitions of ten existing terms. The proposed new or modified definitions would be: Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Informant, Intermediary, Investigative agency, Part 2 program director, Patient, Payment, Person, Program, Public health authority, Qualified service organization, Records, Third-party payer, Treating provider relationship, Treatment, Unsecured protected health information, Unsecured record, and Use. Most of these terms and definitions would be added or modified by referencing existing HIPAA regulatory terms in 45 CFR parts 160 and 164, either in accordance with the adoption of such definitions by section 3221(d) of the CARES Act, which added paragraph (k) (containing definitions) to 42 U.S.C. 290dd–2, or as a logical outgrowth of CARES Act amendments. Several other definitions would be modified for clarity and consistency, as described below. The Department requests comment on all proposals to add new or modify existing definitions to this part.

Breach. The proposed definition of Breach would adopt the Breach Notification Rule definition by reference to 45 CFR 164.402, but as applied to Part 2 records rather than to PHI. The Department proposes this definition to implement paragraph (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 of the term for the purposes of the HIPAA regulations. Because the CARES Act requires Part 2 programs to comply with HITECH Act breach notification requirements, a Part 2 regulatory definition of breach is necessary to implement and enforce these requirements.

Business associate. The Department proposes to adopt the same meaning of this term as is used in the HIPAA Rules. This proposal would implement the new paragraph (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.

Covered entity. The Department proposes to adopt the same meaning of this term as is used in the HIPAA Rule. This proposal would implement the new paragraph (k) of 42 U.S.C. 290dd–

[118] *See* 45 CFR part 160, subparts 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).

[119] 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 Department of Justice has authority to impose criminal penalties where applicable. *See* 68 FR 18895, 18896 (April 17, 2003).

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.

Health care operations. The proposal would incorporate the HIPAA Privacy Rule definition for health care operations.[120]

HIPAA. Although not required by the CARES Act, the Department proposes to add a definition of HIPAA that encompasses the statutory and regulatory provisions pertaining to the privacy, security, breach notification, and enforcement standards with respect to PHI. This definition would exclude other components of the HIPAA statute, such as insurance portability, and other HIPAA regulatory standards, such as the standard electronic transactions regulation, which are not relevant to this proposed rule. The Department proposes this definition to make clear the specific components of the relevant statutes that would be incorporated into this part.

HIPAA regulations. The current rule does not define HIPAA regulations. The proposed definition is based on the statutory definition added by the CARES Act and has the same meaning as ''HIPAA Rules,'' which refers to the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules, when used in this document, OCR rulemaking, and OCR's guidance and other materials. For purposes of this rulemaking, the term does not include Standard Unique Identifiers, Standard Electronic Transactions, and Code Sets, 42 CFR part 162—Administrative Requirements.

Informant. Within the definition of ''informant,'' the Department proposes to replace the term ''individual'' with the term ''person'' as is used in the HIPAA Rules and discussed below.

Intermediary. The current rule uses the term intermediary in § 2.13(d)(2) [121] without providing a definition. To improve understanding of the requirements for intermediaries, and to distinguish those requirements from the proposed accounting of disclosure requirements, the Department proposes to establish a definition of intermediary.

Examples of an intermediary include, but are not limited to, a health information exchange, a research institution that is providing treatment, an accountable care organization, or a care management organization. In contrast, a research institution that is not providing treatment or a health app that is providing individual patients with access to their records would not be considered an intermediary. Member participants of an intermediary refers to health care provider practices or health-related organizations. It does not include individual health plan subscribers or workforce members who share access to the same electronic health record system.

In the current rule, if a patient provides a written consent that is specific to treatment, the general designation of a recipient entity who is an intermediary may be used and the patient would have a right to obtain a list of recipients to whom the intermediary has disclosed their record.

Under section 3221 of the CARES Act, a patient consent may contain a general designation of recipients for treatment, payment, and health care operations. Without regulatory clarification this could result in the recipients exchanging health information through an HIE/HIN or other means without triggering the intermediary requirements. To avoid this unintended consequence, the Department proposes additional changes to § 2.31(a)(4) to ensure that intermediaries continue to be named whenever they are used to exchange Part 2 records.

Under this proposal, an intermediary would be 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. The term intermediary is based on the function of the person—receiving records 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. For example, an electronic health record vendor that enables entities at two different health systems to share records likely would be an intermediary. 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. Where an intermediary is also a business associate under the HIPAA Rules, it would be subject to the requirements of both an intermediary and a business associate.

The requirements for intermediaries would remain unchanged but would be redesignated from § 2.13(d), *Lists of disclosures,* to new § 2.24, *Requirements for intermediaries.* These proposed modifications are discussed separately below.

Investigative agency. The Department proposes to create a new definition for ''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 by law enforcement, the Department proposes 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.'' By creating a definition of investigative agency, the Department does not intend to change the applicability of § 2.53 or subpart E, but only to establish a limitation on liability for such agencies in certain circumstances when a court order is otherwise required by these regulations.

Part 2 program director. Within the definition of ''part 2 program director,'' the Department proposes 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'' as used in the HIPAA Rules and discussed below.

Patient. The Department proposes 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.

Payment. The Department proposes to adopt the same definition for this term as in the HIPAA Rules. This proposal would implement the new paragraph (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.

Person. The term ''person'' is currently defined as ''an individual, partnership, corporation, federal, state or local government agency, or any other legal entity, (also referred to as ''individual or entity'').'' Thus, the current Part 2 regulation uses the term ''individual'' in reference to someone who is not the patient and therefore not the subject of the Part 2 record. In contrast, the HIPAA Rules 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.'' To further the alignment of Part 2 and the

[120] *See* 45 CFR 164.501 (definition of ''Health care operations'').

[121] Section 2.13(d)(2) refers to the description of an intermediary in § 2.31(a)(4)(ii)(B).

HIPAA Rules and provide clarity for programs and entities that must comply with both sets of requirements, the Department proposes 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 also proposes 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 Rules. The Department believes that this combination of modifications would promote the understanding of both Part 2 and the HIPAA Rules and requests comment on whether this or other approaches would provide more clarity.

Program. Within the definition of ''program,'' the Department proposes to replace the term ''individual or entity'' with the term ''person'' as is used in the HIPAA Rules and discussed above.

Public health authority. The Department proposes to adopt the same meaning for this term as in the Privacy Rule. This proposal would implement the new paragraph (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.

Qualified service organization. The Department proposes to modify the definition of Qualified service organization (QSO) 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 believes this proposal would facilitate the implementation of the CARES Act with respect to disclosures to QSOs. The HIPAA Rules 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) [122] without individual authorization, when based on a business associate agreement that incorporates certain protections.[123] 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 proposes 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.

Records. The definition of records specifies the scope of information that Part 2 protects. The Department proposes to remove the last sentence of the definition as unnecessary.[124] In the five decades since the promulgation of the Part 2 regulation, health information technology 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.

The Department offers clarification here about how the definition of Part 2 records operates in relation to the HIPAA definitions of PHI, designated record set, and psychotherapy notes.

These issues are most pertinent with respect to the right individuals have to access their records under the HIPAA Rules, as explained below (Part 2 does not contain a parallel patient right of access to records).

Generally, the HIPAA Privacy Rule gives individuals the right to access all of their PHI in a designated record set.[125] 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.[126] A covered entity's Part 2 records usually fall into 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. In the latter situation, the Part 2 records become PHI when they are received by or for the covered entity, and part of a designated record set. As such, they are subject to the Privacy Rule's right of access requirements.

However, the Privacy Rule right of access excludes psychotherapy notes.[127] If 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 psychotherapy notes as well as Part 2 records. In this case, the individual would not have a Privacy Rule right of access to those records, but a provider may voluntarily provide access upon request by the individual patient. Additionally, psychotherapy notes created by a Part 2 program that is a covered entity could only be disclosed with a separate written authorization or consent.

The Department is considering whether to create a new definition similar to psychotherapy notes 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. The Department solicits 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 Privacy Rule. Under consideration is a definition such as this:

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 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.

As with psychotherapy notes under the Privacy Rule, the separate consent requirement, if adopted, would not apply to SUD counseling notes in the following situations:

1. Use by the originator of the SUD counseling notes for treatment;

[122] *See* 45 CFR 160.103 (definition of ''Business associate'').

[123] *See, e.g.,* 45 CFR 164.504(e).

[124] The last sentence reads ''For the purpose of the regulations in this part, records include both paper and electronic records.'' 42 CFR 2.11 (definition of ''Record'').

[125] *See* 45 CFR 164.524.

[126] *See* 45 CFR 164.501 (definition of ''Designated record set'').

[127] *See* 45 CFR 164.524(a)(1)(i); *see also* 45 CFR 164.501 (definition of ''Psychotherapy notes'').

2. Use or disclosure by the program for its own training programs in which students, trainees, or practitioners in SUD treatment learn under supervision to practice or improve their skills in group, joint, family, or individual counseling;

3. For the program to defend itself in a legal action or other proceeding brought by the patient;

4. Required for the reporting of child abuse or neglect;

5. Required by law;

6. Required for oversight of the originator of the SUD counseling notes;

7. To a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law; or

8. When necessary to lessen a serious and imminent threat to the health or safety of a person or the public and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

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. The current regulation, at § 2.12, limits disclosures by third-party payers to a shorter list of purposes than the Privacy Rule allows for health plans. The Department proposes 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, such as grant-funded programs. 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 proposes 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.

The Department welcomes comments on the number and type of third-party payers that would not be considered health plans.

Treating provider relationship. The Department proposes to modify the Part 2 definition of ''treating provider relationship'' by replacing the phase ''individual or entity'' with ''person,'' in accordance with the proposed changes to the definition of ''person'' described above.

Treatment. The Department proposes to modify the Part 2 definition of ''treatment'' by adopting the Privacy Rule definition by reference. This proposal would implement the new paragraph (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 of the term for the purposes of the HIPAA regulations. By replacing the existing language, the Department does not intend to change the scope of activities that constitute treatment. Thus, it remains true, as provided in the prior definition, that 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, in order to reduce or eliminate the adverse effects upon the patient.

Unsecured protected health information. The Department proposes to adopt the same meaning of this term as used in the HIPAA Rules. This proposal would implement the new paragraph (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 in the purposes of the HIPAA regulations.

Unsecured record. To align with the definition of ''unsecured protected health information'' at 45 CFR 164.402, the Department proposes 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, 13402(h)(2).[128] The Department believes this proposal is necessary to implement the newly required breach notification standards for Part 2 records and requests comment on this approach.

Use. The Department proposes to add a definition for this term that is consistent with that in the HIPAA Rules at 45 CFR 160.103, and as the term is applied to the conduct of proceedings specified in statute at 42 U.S.C. 290dd–2(c). The Department believes this proposal is necessary to more fully align this part with the HIPAA Rules use of the language ''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 proposes this definition to make clear 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 proceedings. The Department discusses in greater detail the addition of the term ''use'' to specific provisions throughout this NPRM, and in particular, in connection to § 2.12 below.

§ 2.12—Applicability

Section 2.12 includes five provisions outlining the scope of the rule's requirements. Paragraph (a) of § 2.12 describes which records are protected and describes the restrictions on use and disclosure of Part 2 records; paragraph (b) outlines what constitutes federal assistance for purposes of the regulation's applicability; paragraph (c) specifies exceptions for certain disclosures; paragraph (d) provides restrictions that apply to: (1) any recipient of Part 2 records, and (2) third-party payers and administrators; and paragraph (e) details the types of records and diagnoses to which the restrictions in this regulation apply.

The Department proposes to amend the Part 2 regulation in paragraph (c)(2) of § 2.12, which excludes from Part 2 requirements certain interchanges of information within the Armed Forces and between the Armed Forces and the Department of Veterans Affairs, by replacing ''Armed Forces'' with ''Uniformed Services.'' This change would align the regulatory text with the statutory language at 42 U.S.C. 290dd–2(e). The change also would create consistency with the Department's proposal to expand the Privacy Rule permission for covered entities, at 45 CFR 164.512(k), to use or disclose the PHI of Armed Services personnel when deemed necessary by certain military command authorities to all Uniformed Services, which would then include the U.S. Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps.[129] As the Department noted in that NPRM to modify the Privacy Rule, the USPHS and 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

[128] *See* the Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals at *https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html.*

[129] *See* proposed 45 CFR 164.512(k) at 85 FR 6446, 6487.

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 requests comment on this assumption.

The Department also proposes to add the term ''use'' to paragraphs (a)(1), (c)(3), (c)(4), and (d)(2) of this section, and the term ''disclosure'' to paragraphs (a)(2) and (d)(1), to make clear that as amended by CARES Act section 3221(b), these provisions include both uses and disclosures that are restricted by Part 2. The Department also proposes to add ''use'' to the second sentence of paragraph (e)(3). 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 Privacy Rule applies the term ''use'' to refer to internal use of health information within an entity, such as access by staff members. With this understanding, a Part 2 record could be both used and disclosed for purposes related to the provision of health care, but also for the purposes such as the initiation of a legal proceeding. To align Part 2 with the Privacy Rule, the Department proposes to adopt the ''use and disclosure'' terminology throughout the regulation when both actions could apply. The Department requests comment on this approach.

The Department also proposes in paragraph (d)(1) of § 2.12 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 to cover civil, administrative, or legislative proceedings in addition to criminal proceedings.[130] Absent patient 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 proposed narrowing of the definition of third-party payer in § 2.11 would exclude covered entity health plans from the limits on redisclosure of Part 2 records in paragraph (d)(2) of § 2.12. To clarify the modified scope of this paragraph, the Department proposes to insert qualifying language in § 2.12(d)(2) 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 Department seeks comment and data on the number and types of third-party payers, as defined in the proposed rule, to which the redisclosure limitations would continue to apply. The Department especially seeks comment on how this provision would apply to grant-funded programs.

The Department proposes 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 [131] 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 proposes to clarify the language in subparagraph (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 believes 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 requests comment on this approach.

The Department proposes 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 it is defined in the Privacy Rule at 45 CFR 160.103.

§ 2.13—Confidentiality Restrictions and Safeguards

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 the part is required by programs and lawful holders and restrict the ability of programs to acknowledge the presence of patients at certain facilities.

To more accurately describe how the regulations of this part apply to the activities of programs after the amendment of 42 U.S.C. 290dd–2 by section 3221 of the CARES Act, and to align the language throughout this section with language in the Privacy Rule, the Department proposes to modify paragraphs (a) and (b) of this section by replacing the phrase ''disclosed or used'' with ''used or disclosed'', and in paragraph (a), adding the term ''use'' in front of the term ''disclosure.'' The Department proposes to add the term ''use'' in paragraph (a) of this section because sections 3221(b) and (e) of the CARES Act amends key provisions of 42 U.S.C. 290dd–2 so that confidentiality restrictions and safeguards apply to both uses and disclosures.

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 a health information exchange (HIE), has disclosed the patient's identifying information pursuant to a general designation. The Department proposes to remove § 2.13(d) and redesignate the content as § 2.24, change the heading to

[130] 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* Administrative Subpoenas in Criminal Investigations: A Brief Legal Analysis, *EveryCRSReport.com*, University of North Texas Libraries Government Documents Department, (December 19, 2012), *https://www.everycrsreport.com/reports/RL33321.html.*

Legislative investigations may also be conducted in furtherance of the functions of Congress or state legislative bodies. *See* ''What, Exactly, Does Congress Have the Authority To Investigate?'' Molo Lamken, LLP 2018, *https://www.mololamken.com/knowledge-What-Exactly-Does-Congress-Have-the-Authority-To-Investigate#:~:text=While%20Congress%20can%20investigate%20conduct,otherwise%20initiate%20a%20criminal%20prosecution.*

[131] The Department proposes to add ''disclosures'' to secs. 2.17(b) and 2.67(d)(3) for the same reason.

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. The Department's proposed change to the heading is intended to distinguish the right to a list of disclosures made by intermediaries from the proposed new right to an accounting of disclosures made by a part 2 program.

In addition to these proposed structural changes, the Department also proposes 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 solicits 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 requests comment on whether it should modify Part 2 to apply the same or similar safeguards requirements to electronic Part 2 records as the Security Rule applies to ePHI or whether other safeguards should be applied to electronic Part 2 records.

§ 2.14—Minor Patients

Current § 2.14 establishes the consent requirements for the disclosure of records of minor patients. To align the description of these requirements with 42 U.S.C. 290dd–2(b), as amended by section 3221(b) of the CARES Act, and to align the language of this provision with the Privacy Rule, the Department proposes to add the term ''use'' in paragraphs (a) and (b) to clarify that requirements related to consent given by minor patients would apply to both uses and disclosures of records. For example, as amended by section 3221(b) of the CARES Act, 42 U.S.C. 290dd–2(b)(1)(A) and (B) require a program or covered entity to obtain the appropriate consent, as determined by this section, to use or disclose the Part 2 records of the minor, and to use or disclose the same records for TPO purposes in accordance with the Privacy Rule. Subsection (c) of this section addresses when a minor's application for treatment may be disclosed to the minor's parents. The Department proposes to change the verb ''judges'' to ''determines'' to describe a program director's evaluation and decision that a minor lacks decision making capacity that could trigger a disclosure to the patient's parents. This change is intended to distinguish between the evaluation by a 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 proposes a technical edit to § 2.14(c)(1) to correct a typographical error from ''youthor'' to ''youth or.''

The Department also proposes to substitute the term ''person'' for the term ''individual'' in § 2.14(b)(1), (b)(2), (c), (c)(1), and (c)(2), 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 it is defined in the Privacy Rule at 45 CFR 160.103.

§ 2.15—Patients Who Lack Capacity and Deceased Patients (Proposed Heading)

Section 2.15 of 42 CFR part 2 addresses who may consent to a disclosure of records when a patient lacks capacity to make health care decisions or is deceased. The Department proposes to replace the outdated term ''incompetent'' and refer instead to patients who lack capacity to make health care decisions. This modification is not intended as a substantive change, but would replace a term that may be considered derogatory. The rule clearly distinguishes between situations involving an adjudication and those without adjudication. Consistent with 42 U.S.C. 290dd–2, as amended by section 3221(b) of the CARES Act, the Department proposes to clarify, by referring to the ''use'' of records in addition to disclosures of records in paragraphs (a)(2) and (b), that confidentiality requirements related to the records of patients who lack the capacity to make health care decisions and deceased patients apply to both uses and disclosures. The Department also proposes to substitute the term ''person'' for the term ''individual'' as discussed above in relation to § 2.11, *Definitions.* The Department further proposes 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 program may disclose records without consent to obtain payment during a period when the patient has an unadjudicated inability to make decisions. Finally, the Department proposes in paragraphs (b)(1) and (b)(2) of this section to clearly identify that the restriction on the ability to use or disclose patient identifying information applies to the Part 2 program.

§ 2.16—Security for Records and Notification of Breaches (Proposed Heading)

Section 2.16, *Security for records,* currently includes a set of 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. Sections 2.16(a)(1)–(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 Department proposes to change the requirements in § 2.16(a) to more closely align them with the Privacy Rule de-identification standard. Specifically, the Department proposes to modify § 2.16(a)(1)(v) (for paper records) and § 2.16(a)(2)(iv) (for electronic records), as follows: ''Rendering patient identifying information de-identified in accordance with the requirements of the 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.'' The Department requests comment on the extent to which Part 2 programs render patient identifying information de-identified under § 2.16(a)(1)(v) and § 2.16(a)(2)(iv) in a manner that differs from the Privacy Rule de-identification standard, such that conforming the Part 2 requirements to the Privacy Rule standard would create unintended adverse consequences for Part 2 programs or patients. In addition, the Department requests comment on examples of situations in which Part 2 programs or covered entities render Part 2 information not readily identifiable but the information is not de-identified in accordance with the Privacy Rule.

The Department's proposals would increase the alignment of regulatory requirements for Part 2 with the Privacy Rule [132] and Breach Notification Rule.[133] The same public policy

[132] 45 CFR part 164 subparts A and E.

[133] 45 CFR part 164 subpart D.

objectives of the Breach Notification Rule as applied to covered entities would be furthered by establishing analogous requirements for Part 2 programs, namely: (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 a breach of records.

The Department proposes 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 45 CFR parts 160 and 164, subpart D, as mandated by section 3221(h) of the CARES Act. In the event of a breach, Part 2 programs would be required to notify the Secretary, affected patients, and in some cases the media, consistent with the Breach Notification Rule.

Section 2.16 applies security requirements for Part 2 records to both Part 2 programs and ''lawful holders.'' The term ''lawful holder'' is enshrined in several Part 2 regulatory provisions [134] but not defined in regulation. Generally, the term refers to ''an individual or entity who has received such information as the result of a part 2-compliant consent (with a prohibition on redisclosure) 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.'' [135]

However, the Department believes that the requirements of this section do not currently apply uniformly across all persons who receive Part 2 records pursuant to consent and therefore qualify as ''lawful holders'', such that a failure to have ''formal policies and procedures'' or to ''protect'' against threats would result in the imposition of civil or criminal penalties. The Department does not propose to expand the existing scope of persons who are liable for noncompliance with requirements that are applicable only to Part 2 programs and lawful holders. Instead, due to the variety of persons that could receive Part 2 records based on a valid written Part 2 consent, the Department would determine the extent of the duty and ability of a particular person to ''reasonably protect against unauthorized uses'' and against ''reasonably anticipated threats or hazards'' based on the facts and circumstances.

The Department requests comment on its assumptions, and examples of persons who are lawful holders under the existing regulation, but who may not be appropriately held liable for compliance with the administrative requirements for protecting Part 2 records they have received (*e.g.,* policies and procedures to protect against unauthorized use or disclosure) or providing breach notification, such as a patient's family members. The Department also requests comment on whether it would be helpful to create a regulatory definition of ''lawful holder'' and what persons such definition should encompass.[136]

The Department further requests public comment regarding the estimated burden of notification, potential regulatory flexibilities for Part 2 programs to minimize burdens during their initial implementation of the policies and procedures required by the breach notification proposal, and the characteristics of programs to which any suggested flexibilities should apply. In addition, the Department welcomes comments from Part 2 programs that are not covered entities on whether they look to the Security Rule generally for guidance on protecting electronic Part 2 records or otherwise voluntarily attempt to follow the requirements of the Security Rule. For any programs that may do so, the Department requests comment on what their experience has been, including any implementation costs.

§ 2.17—Undercover Agents and Informants

The current provision prohibits, absent court order, a Part 2 program from knowingly employing or enrolling a patient as an undercover agent and restricts the use of information obtained by an undercover agency in any criminal investigation against any patient. To fully implement 42 U.S.C. 290dd–2(c)(3), as amended by section 3221(e) of the CARES Act, The Department proposes to add ''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.

§ 2.19—Disposition of Records by Discontinued Programs

Current § 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 proposes 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 Indian Self-Determination and Education Assistance Act (ISDEAA), in order 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. For example, in the event the Department needs to take over operations of a such a program on short notice, the program records would remain intact, permitting the Department to ensure continuation of services. Without this provision, program records would be destroyed if patient consent is unavailable at the time services are transferred to the Department, which could occur without sufficient opportunity to seek consent from all current or former patients. The Department also proposes 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.

§ 2.20—Relationship to State Laws

Current § 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. The Department proposes to add the term ''use'' to § 2.20 to clarify that this section applies to both uses and disclosures under Part 2 and state law. The Department believes this proposal is consistent with 42 U.S.C. 290dd–2, as amended by section 3221(b) CARES Act, which imposes requirements related to the use and disclosure of Part 2 records.

[134] *See, e.g.,* 42 CFR 2.31, 2.33, 2.52, and 2.53.

[135] *See* 82 FR 6052, 6068. *See also* 81 FR 6988, 6997.

[136] For example, in the Consideration of Regulatory Alternatives section of this NPRM, the Department describes the entities it considered expressly including in a definition that would be codified in regulatory text, including covered entities, business associates, qualified service organizations, and others.

Records subject to regulation by Part 2 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 SUD [137] (and often other issues commonly considered sensitive, such as reproductive health, HIV, or serious mental illness).[138] The Department assumes 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 requests comment on this assumption and 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.

§ 2.21—Relationship to Federal Statutes Protecting Research Subjects Against Compulsory Disclosure of Their Identity

The current language of § 2.21 recognizes the potential for concurrent coverage of certain federal laws that regulate patient identifying information. The Department proposes to reorder ''disclosure and use'' to read ''use and disclosure'' to better align the wording of this section with language used in the Privacy Rule.

§ 2.22—Notice to Patients of Federal Confidentiality Requirements; and 45 CFR 164.520—Notice of Privacy Practices for Protected Health Information

Section 3221(i) of the CARES Act directs the Secretary to modify or ''update'' the HIPAA NPP requirements at 45 CFR 164.520 [139] 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). The CARES Act notice requirements would therefore apply to entities that are subject to both Part 2 and HIPAA, which include covered entities that are Part 2 programs as well as covered entities that receive Part 2 records from a Part 2 program.

The Privacy Rule, at 45 CFR 164.520, establishes an individual right to receive an NPP, written in plain language, providing adequate notice of a covered entity's privacy practices and obligations with respect to individuals' PHI. Health care clearinghouses, correctional institutions that are covered entities, and certain group health plans [140] are excepted from the requirement, but other covered health plans and covered health care providers that maintain a direct treatment relationship [141] with an individual must provide the individual with adequate notice about how the covered entity may use and disclose the individual's PHI, as well as the individual's rights and the covered entity's obligations with respect to the individual's PHI.

To implement section 3221(i)(2) of the CARES Act, the Department proposes to modify both the Patient Notice requirements at § 2.22 and the NPP requirements at 45 CFR 164.520 to provide notice requirements for all Part 2 records. While the CARES Act only expressly requires the modification of the NPP requirements at 45 CFR 164.520, the Department proposes to also modify the Part 2 Patient Notice at § 2.22 to align more closely with the NPP requirements. The proposal to modify § 2.22 would ensure that patients of Part 2 programs that are not covered by HIPAA are afforded as much notice and transparency as is provided to individuals in the NPP. Accordingly, the Department proposes to modify § 2.22 pursuant to the Secretary's authority under 42 U.S.C. 290dd–2(g) to prescribe regulations to carry out the purposes of that section.

The Department also believes there is a statutory mandate to modify the NPP requirements for some HIPAA covered entities that are not Part 2 programs, namely, those covered entities that receive and maintain Part 2 records, and thus are obligated to comply with certain Part 2 requirements with respect to such records. Covered entities that receive and maintain Part 2 records would need to add a provision to their NPP that references the restrictions on use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings against the individual. The current NPP requirements would continue to apply, without change, to covered entities that do not receive or maintain Part 2 records. The proposed changes to § 2.22, notice of federal confidentiality requirements, for Part 2 programs that are not covered entities, followed by proposed changes to 45 CFR 164.520 for covered entities that are dually subject to HIPAA and Part 2, and for other covered entities that receive and maintain Part 2 records, are described below.

Consistent with the requirements of section 3221(i)(2) of the CARES Act, the Department proposes to revise the Patient Notice at § 2.22 of this part, and to update NPP requirements using plain language that is easily understandable and parallel to changes proposed in the NPRM modifying the Privacy Rule published on January 21, 2021.[142] The Department specifically requests comment from legal, clinical, privacy, and civil rights experts on whether the below proposals achieve this goal.

1. Modifying the § 2.22 Patient Notice

Because the HIPAA Rules and Part 2 cover different, but often overlapping, sets of regulated entities, and because the NPP currently offers more robust notice requirements than the Patient Notice, the Department proposes to modify § 2.22 to provide the same information to individuals under the Privacy Rule as to patients of Part 2 programs. The Department's proposed modifications to the Patient Notice would also restructure it to substantially mirror the structure of the NPP. As discussed below, instead of the Patient Notice containing elements described as a ''summary'' of the federal law that applies to protect Part 2 records, the Patient Notice would address the same key elements of the HIPAA NPP such as a required Header, Uses and Disclosures, Individual Rights, and Duties of Part 2 Programs. As further discussed below, the Department proposes to add to the Patient Notice key features of the NPP, such as explaining to patients that they may file a complaint when they believe their privacy rights have been violated, and that they have the right to revoke their consent for Part 2 programs to disclose records in certain circumstances. The Department believes this approach would best implement the intent of Congress to apply NPP protections to these records and requests comment on this approach, including any burdens associated with this approach.

Part 2 programs should be mindful that federal civil rights laws require certain entities, including recipients of federal financial assistance and public

[137] *See e.g.,* Mich. Comp. Laws §§ 333.6111 (expressly excluding SUD records from an emergency medical service as restricted); and NJ Rev. Stat. § 26:2B–20 (2013) (requiring records to be confidential except by proper judicial order whether connected to pending judicial proceedings or otherwise).

[138] *See e.g.,* MO Rev. Stat. § 191.731 (requiring SUD records of certain pregnant women remain confidential).

[139] Section 3221(i) requires the Department to consult with legal, clinical, privacy and civil rights experts. The Department has completed this consultation as part of its internal review process with the identified experts.

[140] *See* 45 CFR 164.520(a)(2) and (a)(3).

[141] *See* 45 CFR 164.501 (definitions of ''Direct treatment relationship'' and ''Indirect treatment relationship).

[142] *See* Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446.

entities, to take appropriate 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.[143] 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.[144]

Section 2.22, *Notice to patients of federal confidentiality requirements,* requires a Part 2 program, at the time of admitting a patient to the program,[145] to give written notice of and summarize the federal law and regulations that protect the confidentiality of SUD records. Section 2.22(b) requires that the notice include five elements: (1) a general description of the limited circumstances in which a Part 2 program may share information that would identify the patient as having or having had a SUD; (2) a statement informing the patient that violation of the federal law and regulations is a crime and contact information for the appropriate authorities; (3) a statement that information related to a patient's commission of a crime on the premises is not protected as confidential; (4) a statement that reports of suspected child abuse and neglect made under state law to appropriate state or local authorities are not protected; and (5) a citation to the federal law and regulations. Finally, § 2.22 gives the option to a Part 2 program to include information about applicable state law and its own local policies. Although § 2.22 does not expressly apply to covered entities and PHI, any covered entity that uses or discloses Part 2 SUD records would be subject to the notice requirements of § 2.22 in addition to the NPP requirements in 45 CFR 164.520. Conversely, Part 2 programs that are not covered entities and not subject to HIPAA would only be obligated to comply with § 2.22.

The Department proposes to modify § 2.22 by incorporating most of the notice requirements in the HIPAA NPP at 45 CFR 164.520, and then excluding those that are non-applicable or pose special privacy risks, and separately addressing certain provisions that have special requirements or differences between application to covered entities and part 2 programs as specified in 42 U.S.C. 290dd–2, as amended by the CARES Act. The Department proposes the following with respect to the Patient Notice at § 2.22.

Header. The Department proposes to require Part 2 programs to include a header in the Patient Notice. The header would be nearly identical to the header required in the NPP (and as proposed for amendment above) at 45 CFR 164.520(b)(1)(i)[146] 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.

Uses and Disclosures. The Department proposes to require a Part 2 program to include in the Patient Notice descriptions of uses and disclosures that are permitted for TPO, permitted without written consent, or will only be made with written consent. Consistent with the current set of NPP requirement for covered entities, the Department proposes to add a 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 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 believes it prudent to propose new § 2.22(b)(1)(iii). This proposal would require that a program provide notice to patients that the program must obtain written consent before it may use or disclose records for fundraising on behalf of the program. This new notice requirement is consistent with a newly proposed consent requirement at § 2.31(a)(5) in which a program must obtain a patient's permission for such uses and disclosures.

Before proposing the approach above, the Department first considered whether to propose a consent requirement for both de-identification and fundraising and whether to structure it as an opt-in or an opt-out. The Department believes that an opt-in requirement would afford patients a greater amount of control over their records and best fulfill patients' expectations about how their Part 2 information would be protected. However, the Department believes that requiring patient consent for de-identification activities would be inconsistent with the new permission to disclose de-identified information for public health purposes as provided in section 3221(c) of the CARES Act. Such a requirement also would create a barrier to de-identification that may negatively affect 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. As noted above, the Department believes uses and disclosures for fundraising warrant this added privacy protection, consistent with congressional intent as expressed in the Sense of Congress.

Individual Rights. The Department proposes to require that a Part 2 program include in the Patient Notice statements of patients' rights with respect to Part 2 records. The structure would mirror the statements of rights required in the NPP for covered entities and PHI but, based on amended 42 U.S.C. 290dd–2, would include:

- Right 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) and when a Part 2 program must agree to a request.
- Right to 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.
- Right to an accounting of disclosures of electronic Part 2 records for the past 3 years, as provided in 42 U.S.C. 290dd–2(b)(1)(B) and right to an accounting of disclosures of Part 2 records that mirrors the right in the Privacy Rule at 45 CFR 164.528.
- Right to obtain an electronic or non-electronic copy of the notice from the program upon request.
- Right to discuss the notice with a designated contact person identified by the program pursuant to paragraph 45 CFR 164.520(b)(1)(vii).

Part 2 program's duties. The Department proposes to incorporate into the Patient Notice statements describing

[143] *See* 45 CFR 92.102 (Section 1557 of the Affordable Care Act); 45 CFR 84.4(b), 84.52(a), (c), (d) (Section 504 of the Rehabilitation Act of 1973); 28 CFR 35.160(a)–(b) (Title II of the Americans with Disabilities Act).

[144] *See* 45 CFR 92.101 (Section 1557 of the Affordable Care Act); 45 CFR 80.3(b) (Title VI of the Civil Rights Act of 1964).

[145] In the event a patient lacks capacity at the time of admission, 42 CFR 2.22(a) alternatively requires that such notice be given as soon as the patient attains capacity.

[146] The Department proposed to modify the NPP header in a separate Privacy Rule NPRM, as described at 86 FR 6446, 6485. The proposed regulatory text herein reflects the changes proposed in the earlier NPRM, as well as new proposed changes.

the duties of Part 2 programs with respect to Part 2 records that parallel the statements of duties of covered entities required in the 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 proposes 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. These statements would 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.[147]

Contact and Effective Date. The Department proposes to require that the Patient Notice provide the name or title, telephone number, and email address of a person a patient may contact for further information about the Part 2 Notice, and information about the date the Patient Notice takes effect. These provisions would parallel requirements for the NPP.

Optional Elements. The Department proposes to incorporate into the Patient Notice the optional elements of an 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 proposes 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. These provisions would parallel requirements for the NPP.

Implementation Specifications. The Department proposes to require that a Part 2 program provide the Patient 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 Patient Notice be provided as soon as reasonably practicable after emergency treatment. Finally, if the Part 2 program has a physical delivery site, the Patient 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, if it has one. These provisions would parallel the requirements for provision of the NPP by covered health care providers.[148]

The Department requests comment on each Patient Notice proposal, including information on how incorporating NPP elements into the Patient Notice requirements would increase or alleviate burdens for Part 2 programs.

2. Modifying 45 CFR 164.520

Applying the NPP requirements to certain entities. Section 3221(i)(2) of the CARES Act requires the Department to update the NPP to provide notice of privacy practices with respect to Part 2 records being created or maintained by ''covered entities and entities creating or maintaining the records described in subsection (a)'' (referring to section 543(a) of the PHSA, 42 U.S.C. 290dd–2(a), specifying and defining Part 2 records). The Department proposes all of the following changes to 45 CFR 164.520 to update it in accordance with the CARES Act and to ensure adequate notice is given to patients who are the subject of these records.

The Department proposes to modify 45 CFR 164.520(a) by adding a new paragraph (2) to expressly apply the NPP provisions to covered entities using and disclosing Part 2 records. The proposed change would further align the Patient Notice requirements for Part 2 records with NPP requirements with respect to PHI.

The Department also proposes to remove paragraph (3) of 45 CFR 164.520(a), *Exception for inmates.* The Department no longer believes it is appropriate to withhold notice from an incarcerated individual with respect to their health information privacy rights and a covered entity's practices. When the Department finalized the exception, it stated ''[n]o person, including a current or former inmate, has the right to notice of such a covered entity's privacy practices'' seeming to distinguish correctional facilities that are covered entities from other covered entities. The Department is unable to discern a safety or security risk associated with providing inmates notice concerning the covered entity correctional institute's privacy practices for PHI. This proposal would ensure that regulated entities provide an NPP to inmates consistent with what is provided to other individuals and retains the limitation on the right of access due to security concerns.

Content of Notice requirements apply to all covered entities, including those that are also subject to Part 2. The Department proposes to amend the required Header at 45 CFR 164.520(b)(1) to specifically reference covered entities maintaining or receiving Part 2 records. In addition, the proposed regulatory text at 45 CFR 164.520(b)(1)(i) reflects the changes to 45 CFR 164.520 previously proposed in the NPRM to Modify the Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, published in 2021.[149] Further, in 45 CFR 164.520(b)(1)(i) and in § 2.22, the Department proposes to change the word ''Medical'' to ''Health'' to refer to the type of information covered by the NPP. This change is not intended to modify substantive requirements, but instead is proposed to more accurately reflect and clarify that the information covered by the notice is not limited to the information a covered entity places in an individual's medical record.

Description of Uses and Disclosures. Section 3221(i)(2)(B) of the CARES Act requires the updated NPP for Part 2 records to include descriptions for every purpose for which the covered entity is permitted or required to use or disclose PHI without the patient's written authorization, ''as required by subsection (b)(2) of such section 164.520.'' However, 45 CFR 164.520(b)(2) sets out optional elements for the NPP and does not address uses or disclosures that are permitted or required without the individual's authorization. Therefore, the

[147] *See* 42 U.S.C. 290dd–2(f) and 42 U.S.C. 1320d–5.

[148] *See* 45 CFR 164.520(c)(2)(i)(A), (c)(2)(i)(B), (c)(2)(iii)(B). See also proposed amendments to this section in the NPRM to Modify the Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446.

[149] *See* 86 FR 6446.

Department believes that the drafters of the CARES Act provision intended to refer instead to 45 CFR 164.520(b)(1)(ii), which requires that the NPP include descriptions of Uses and Disclosures, including a description of each use or disclosure that is permitted or required without the individual's written authorization.[150]

The Department proposes to add to the description in 45 CFR 164.520(b)(1)(ii)(C) and (D) the language ''such as 42 CFR part 2'' to ensure that covered entities understand their specific obligation to address restrictions placed on the use and disclosure of Part 2 records.

Section 164.520(b)(1)(iii) includes requirements for *Separate statements for certain uses or disclosures.* In the introductory paragraph of this sub-section, the Department proposes to add ''or (B)'' to include sub-paragraph (B) in the list of descriptions that require a separate statement to describe TPO uses and disclosures under 45 CFR 164.520(b)(1)(ii)(A) or those made without authorization under 45 CFR 164.520(b)(1)(ii)(B). The Department also proposes to add new sub-paragraph (D) providing notice that Part 2 records or testimony relaying the content of such records shall not be used or disclosed in certain proceedings against the individual without written consent or court order, and new sub-paragraph (E) providing notice that if a covered entity that is a Part 2 program intends to engage in activities addressed in the Sense of Congress in section 3221(k)(4) of the CARES Act,[151] the program must first obtain the patient's express written consent. This provision would support the implementation of 42 U.S.C. 290dd–2(c).

Statement of Rights. Section 3221(i)(2)(A) of the CARES Act requires the NPP for Part 2 records to include a statement of the patient's rights with respect to PHI and how the individual may exercise such rights as required by 45 CFR 164.520(b)(1)(iv). The statement must address the rights of patients who self-pay (*i.e.,* cash or other payment not billed to a third-party payer or health plan).

Current 45 CFR 164.520(b)(1)(iv) requires a covered entity to include in its NPP a statement of an individual's rights with respect to PHI. To implement the CARES Act requirements related to a Statement of Rights, the Department proposes to revise 45 CFR 164.520(b)(1)(iv)(C), to require a covered entity, when providing notice about the right of access, to include notice about the right to inspect and obtain a copy of PHI, the right to do so at limited cost or free of charge, and the right to direct a covered health care provider to transmit an electronic copy of PHI in an electronic health record to a third party. The Department also proposes to add a new § 164.520(b)(1)(iv)(G) to require a covered entity to provide notice of the right to discuss the NPP with a designated contact person identified by the covered entity. These changes are made to reflect the changes to the NPP provisions proposed by the Department in the NPRM to Modify the Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement.[152]

Covered entity's duties. The Department proposes, at 45 CFR 164.520(b)(1)(v)(A), to remove the second reference to ''protected health information'' to expand the requirement that a covered entity provide individuals with notice of the covered entity's legal duties and privacy practices to information beyond that of PHI (*i.e.,* to Part 2 records). The Department proposes to modify 45 CFR 164.520(b)(1)(v)(C), a provision that addresses a covered entity's right to change the terms of its NPP, to simplify the text, remove the reference to the administrative requirements of the Privacy Rule (*i.e.,* so that it also applies to Part 2), and insert a limitation that any new terms must not be material or contrary to law.

Other proposed updates to the NPP. The Department proposes other changes to conform the NPP requirements at 45 CFR 164.520 to changes required by the CARES Act. For example, the Department proposes to modify 45 CFR 164.520(b)(1)(iii) to address the Sense of Congress expressed at 42 U.S.C. 290dd–2(k)(4). Although the Sense of Congress does not give legal effect to the exclusion of fundraising and the creation of de-identified health information and limited data sets as permissible disclosures under ''health care operations'', the Department believes that fundraising is far enough outside an individual's reasonable expectation of how their Part 2 records will be used or disclosed that entities should obtain written consent. This means that the NPP provision at 45 CFR 164.520(b)(1)(iii) would still give notice to individuals that a covered entity may use or disclose the individual's PHI for fundraising with an option to opt out of such communications. However, in the case of a covered entity that is also a Part 2 program, it would also provide notice that a covered entity may use or disclose the individual's Part 2 records for fundraising on behalf of the covered entity only with the written consent of the individual. The Department also proposes to incorporate changes proposed to the NPP requirements in the NPRM to Modify the Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement.[153] These proposals include adding a requirement, at 45 CFR 164.520(b)(1)(vii), that a covered entity's NPP include the email address for a designated person who would be available to answer questions about the covered entity's privacy practices; adding a permission for a covered entity to provide information, in its NPP, concerning the right to direct copies of PHI to third parties when the PHI is not in an EHR and the ability to request the transmission using an authorization; and removing the existing requirement for a covered entity to obtain a written acknowledgement of receipt of the NPP. Finally, the Department proposes a new paragraph at 45 CFR 164.520(d)(4) to prohibit construing the permissions for OHCAs to disclose PHI between participants as negating obligations related to Part 2 records.

The Department is mindful of the compliance burden imposed on all entities due to NPP requirements. The Department carefully considered how to accomplish the CARES Act mandate to update the NPP and believes that the proposed changes to 45 CFR 164.520 implements the statutory requirement to inform individuals in a manner that places the least burden on regulated entities. The Department requests comment on this assumption.

§ 2.23—Patient Access and Restrictions on Use and Disclosure (Proposed Heading)

The Department proposes to add the term ''disclosure'' to the heading of this section and throughout paragraphs (a) and (b) to clarify that a patient is not required to provide written consent or authorization in order to access their own Part 2 records. The Department proposes additional wording changes to this section to improve readability and to replace the word ''information'' to ''records,'' which more accurately describes the scope of the information to which the regulation applies.

[150] *See* 45 CFR 164.520(b)(ii)(A)–(D).

[151] Section 3221(k)(4) expresses the Sense of Congress that creating de-identified health information, a limited data set, and fundraising for the benefit of a covered entity should be excluded from the definition of health care operations as applied to the use and disclosure of Part 2 records.

[152] *See* 86 FR 6446.

[153] *Id.*

§ 2.24—Requirements for Intermediaries (Redesignated and Proposed Heading)

Under § 2.13(d), a patient has a right to request a list of disclosures made by an intermediary; the intermediary must provide the patient with information regarding disclosures made within the past two years. As described above in §§ 2.11 *Definitions* and 2.13 *Confidentiality restrictions and safeguards,* the Department proposes to remove paragraph (d) of § 2.13 and redesignate it as § 2.24; change the subheading from *Lists of disclosures* to a heading titled *Requirements for intermediaries;* and in § 2.11 create a regulatory definition of the term ''intermediary''. The Department proposes modifications to clarify the newly designated § 2.24 without intending to change the obligations of intermediaries, other than the time period covered by the list of disclosures.

Specifically, the Department proposes to replace the description of intermediaries with a new regulatory definition and to move the statement of responsibility for complying with the applicable requirements from the end of the provision to the beginning. The intent is to clarify what types of entities would be considered intermediaries—*e.g.,* HIEs, research institutions, accountable care organizations, and care management organizations—and their responsibilities for providing patients with a list of disclosures made to member or participant treating providers. An intermediary may be a business associate when a Part 2 program is also a covered entity under HIPAA; in such situations, the intermediary would be subject to requirements of intermediaries as well as those for business associates. The Department proposes to extend the period covered by a list of disclosures from two years to three years to align with the new right to an accounting of disclosures as proposed in § 2.25(b) for disclosures made for purposes of treatment, payment, and health care operations, discussed below. The Department also proposes modifications to the redesignated section to improve clarity and understanding without intending any substantive change.

§ 2.25—Accounting of Disclosures (Proposed Heading)

Except for disclosures made by intermediaries, the existing Part 2 regulation does not include a right for patients to obtain an accounting of disclosures of Part 2 records.[154] 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 proposes 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 would apply to the individual right to an accounting of disclosures in the HITECH Act.[155] The first paragraph of the section, (a), would generally require an accounting of disclosures made with patient consent, and the second paragraph, (b), would limit the requirement with respect to disclosures made with consent for TPO purposes, which would only be required for TPO disclosures made from an electronic health record system. In both instances, the proposed changes would be contingent on the promulgation of HITECH Act modifications to the accounting of disclosures standard in the Privacy Rule at 42 CFR 164.528.[156]

The Department believes this approach is consistent with section 3221(b) of the CARES Act, 42 U.S.C. 290dd–2(b)(1)(B), as amended. The Department notes that the CARES Act applied the HITECH Act timelines and structure for accounting of disclosures to ''all disclosures'' and not just those disclosures of PHI contained in an EHR. From a policy perspective the Department believes it is appropriate apply the regulatory framework to all accountings.

Because the Department has not yet finalized the HITECH Act accounting of disclosures modifications within the Privacy Rule, the Department does not intend to apply requirements similar to 45 CFR 164.528 before finalizing the Privacy Rule provision. The Department seeks comment on this approach to aligning the accounting of disclosures requirements of the Privacy Rule and Part 2 by incorporating a general requirement for an accounting of disclosures and a limited requirement with respect to TPO disclosures, and by tolling the effective date of the accounting of disclosures proposals in this rule until the effective date of the modified Privacy Rule accounting provision. Additionally, the Department requests data from Part 2 programs that are also covered entities or business associates on the number and type of requests for an accounting of disclosures of PHI received annually and to what extent such covered entities are providing an accounting of disclosures for TPO disclosures through an electronic health record based on the HITECH Act statutory requirement, even absent regulations. For Part 2 programs that are covered entities, the Department requests comments concerning the staff time and other costs involved in responding to an individual's request for an accounting of disclosures of PHI.

§ 2.26—Right to Request Privacy Protection for Records (Proposed Heading)

The existing Part 2 regulation does not expressly provide a patient the right to request restrictions on disclosures of Part 2 records. Section 3221(b) of the CARES Act amended the PHSA to apply section 13405(a) of the HITECH Act, *Restricted restrictions on certain disclosures of health information,* to all disclosures of Part 2 records for TPO purposes with prior written consent. Therefore, the Department proposes to codify in § 2.26 patient 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,[157] as implemented in the Privacy Rule at 45 CFR 164.522. As with the Privacy Rule right to request restrictions, a covered entity that denies a request for restrictions still would be

[154] 42 CFR 2.13(d) (specifying List of Disclosures requirement applicable to intermediaries).

[155] OCR published an NPRM to implement this HITECH Act provision in 2011 but did not finalize it because of concerns raised by public comments. 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 RFI. *See* 83 FR 64302, 64307 (December 14, 2018). A final HIPAA rule on the accounting of disclosures that would apply to TPO disclosures by covered entities has not been issued.

[156] *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 Request for Information (RFI) at 75 FR 23214 (May 3, 2010) and an NPRM at 76 FR 31426 (May 31, 2011). Based in part on public comment the RFI, the Department proposed to provide individuals with an ''access report'' as a means of fulfilling the requirement. Based on feedback to the NPRM in which commenters overwhelmingly opposed the report as ''unworkable,'' the Department, in a follow up RFI published at 83 FR 64302 (December 14, 2018), explained its intent to withdraw the proposal of the 2011 NPRM. The Department received additional public comment about implementing sec. 13405(c) and has recently published, in the Spring 2021 Regulatory Unified Agenda, an intent to publish a second RFI seeking further comment on this HITECH ACT section, *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0945-AA04.*

[157] *See* 42 U.S.C. 17935(a).

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 Privacy Rule to request restrictions on the use or disclosure of Part 2 records for TPO; [158]

(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; [159] 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.[160]

The Department requests comments and data on the extent to which covered entities currently 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.

Subpart C—Uses and Disclosures With Patient Consent (Proposed Heading)

The Department proposes to modify the heading of Subpart C from ''Disclosures with Patient Consent'' to ''Uses and Disclosures with Patient Consent'' to make the heading consistent with the changes the Department proposes to this subpart.

§ 2.31—Consent Requirements

The Part 2 consent provision in current § 2.31 specifies in paragraph (a) the required elements of a valid written patient consent for the disclosure of Part 2 records, and in paragraph (b) what constitutes a deficient consent upon which a disclosure of Part 2 records is not permitted. To further align Part 2 with the Privacy Rule and implement the requirements of section 3221(b) of the CARES Act, the Department proposes numerous changes to the consent requirements in paragraph (a). Specifically, the Department proposes to change requirements concerning:

- Identity of the discloser
- Description of the information to be disclosed
- Designation of the recipient
- Purpose of the disclosure
- Right to revoke consent
- Expiration of consent

In addition, the Department proposes new required statements as part of a consent for use and disclosure for TPO and a new required statement about the consequences to the patient of a failure to sign a consent.

The Department also proposes to add the phrase ''use or'' in § 2.31(a), and ''used or'' in § 2.31(a)(4)(ii)(B), to clarify that the elements of a written consent would address both use and disclosure of records. The Department believes these proposals are consistent with section 3221(b) of the CARES Act, which addresses permissions and restrictions for both uses and disclosures of records for TPO by programs and covered entities. The Department also proposes a wording change to replace the phrase ''individual or entity'' and the term ''individual'' with the term ''person'' as now proposed to comport with the meaning of the term in the HIPAA Rules. The Department does not believe that as amended, 42 U.S.C. 290dd–2 diminishes the ability of a patient to only grant consent for disclosure of specific types of information contained in the Part 2 record or for specific TPO purposes. Additionally, the proposed change to the designation of a recipient would continue to permit patients to, for example, name a government agency to receive records when applying for public benefits and not require the name of a specific employee within the agency.

The Department notes the permission enacted in 42 U.S.C. 290dd–2(b)(1)(B), as amended by section 3221(b) of the CARES Act, allows that the contents of Part 2 records ''may,'' and are not required, to be used or disclosed in accordance with the Privacy Rule for TPO (after prior written consent is obtained). The Department believes therefore, that the revised statute still permits the disclosing entity to employ more granular consent provisions. Further, the rules of construction in section 3221(j)(1) of the CARES Act support the continued ability of covered entities to obtain consent by stating that nothing in the Act shall be construed to limit ''a covered entity's choice, as described in section 164.506 of title 45, Code of Federal Regulations, or any successor regulation, to obtain the consent of the individual to use or disclose a record referred to in such section 543(a) to carry out treatment, payment, or health care operation.''

The Department also notes that its proposal to modify § 2.31(a)(3) would still require the consent form to include a description of the information to be used or disclosed that identifies the information ''in a specific and meaningful fashion.'' [161] This language mirrors that in the Privacy Rule standard for written authorization requiring that a valid authorization pursuant to 45 CFR 164.508 contain ''at least . . . [a] description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.'' [162] The Department believes that its treatment of consent requirements here remains consistent with that of SAMHSA's prior expressed guidance.[163] The Department requests comment on this assumption.

Several of the proposed changes to the language of the required consent elements are not intended to create substantive changes, but merely to align with the wording of similar requirements in the Privacy Rule. This includes, for example, the identity of the discloser, the description of the information to be disclosed, the right to revoke consent, and the expiration of consent.

To fully accomplish the aims of the right to revoke consent, the Department expects that Part 2 programs would need to ensure that any ongoing or automatic disclosure mechanisms are halted upon receipt of a request for revocation. The CARES Act redisclosure permission for a covered entity, business associate, and Part 2 program recipients of Part 2 records limits the ability to ''pull back'' Part 2 information from those entities once it is disclosed. Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, or business associate with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities. It 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 Privacy Rule.

Another set of proposals in this section address general designations of the recipient of Part 2 records for TPO, which may be an intermediary or a Part 2 program, covered entity or business associate. To accommodate TPO written consents, the recipient may be a class of

[158] CARES Act, sec. 3221(j)(1). The Department believes the effect of this Rule of Construction is that 45 CFR 164.522 of the Privacy Rule continues to apply without change to covered entities with respect to Part 2 records.

[159] CARES Act, sec. 3221(k)(2).

[160] CARES Act, sec. 3221(k)(3).

[161] *See* proposed 42 CFR 2.31(a)(3).

[162] *See* 45 CFR 164.508(c) for the complete set of implementation specifications that apply to written authorization under the Privacy Rule.

[163] *See e.g.,* 82 FR 6052, 6087.

persons, rather than only an identified person. In addition, for a single consent for all future uses and disclosures for TPO, 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.

The proposed changes to the requirements for general designation of an intermediary would clarify and simplify the subheading and remove the required statement of the patient's right to a list of disclosures made by the intermediary for the prior two years. These changes are proposed in conjunction with the proposal to add a regulatory definition of intermediary that includes as examples the types of entities listed in § 2.31 and described in previous Part 2 rulemaking preamble discussions.[164] Additionally, the Department proposes to add consent requirements that are similar to the Privacy Rule authorization elements at 45 CFR 164.508, with modifications to address the Part 2 requirement to obtain prior written consent for TPO uses and disclosures. Specifically, the Department proposes to require Part 2 programs to inform patients in the written consent of the potential for their Part 2 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 to be further used or disclosed by the recipient to the extent permitted by the Privacy Rule and no longer protected by this regulation.

However, the Department does not propose to require, similar to the Privacy Rule at 45 CFR 164.522 that a written consent inform patients of the ability, under certain circumstances, to condition treatment on signing a consent for the use or disclosure of Part 2 records, because Part 2 does not prohibit the conditioning of treatment. For example, 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.

The Department is aware of public uncertainty about when a patient consent is considered ''written'' under § 2.31. In previous guidance, SAMHSA clarified that an electronic signed consent form is allowable.[165] The Department reaffirms the previous guidance concerning signatures and further clarifies that, where the Department has issued regulations adopting electronic standards to be used for patient consent management,[166] and Part 2 programs have implemented such standards, the information conveyed using those standards would constitute a ''written'' patient consent where the individual provides all of the information required for a valid patient consent under § 2.31.

Regarding revocation of consent, the proposed changes reflect the text of the CARES Act with respect to TPO consent and also parallels the language of 45 CFR 164.508(c)(2)(i) for the core elements of a HIPAA authorization, which requires a statement about ''[t]he individual's right to revoke the authorization in writing.'' The intent in this section is to align the Part 2 consent requirements with the HIPAA authorization core elements to the extent feasible by establishing written revocation as a patient right. However, a Part 2 program still may accept an oral revocation of consent. Consistent with HIPAA, if an entity receives a revocation orally, the entity ''knows'' that the consent has been revoked and can no longer treat the consent as valid under Part 2 and must consider it deficient under § 2.31(b)(3).[167] For oral revocations, the Department recommends the program obtaining the revocation document the revocation in the patient's record.

The Department's proposal to replace an ''expiration date, event, or condition'' with an ''expiration date or an expiration event that relates to the individual patient or the purpose of the use or disclosure'' is not intended to create substantive change, but only to align with the HIPAA authorization required elements. The Department believes that a ''condition'' may be considered an event that relates to the individual patient. Further, the Department believes the modified language would continue to serve an aim of both the HIPAA and Part 2 expiration elements, which is to ensure that the consent or authorization will last no longer than necessary to accomplish the purpose of the use(s) or disclosure(s).

The Department requests comments on its proposals that would implement changes to § 2.31. Specifically, the Department requests comment on whether there are other changes that it should make to further align § 2.31 with the Privacy Rule using its general regulatory authority in § 3221(i)(1) of the CARES Act to ''make such revisions to regulations as may be necessary for implementing and enforcing the amendments.'' In particular, the Department seeks comment from the public, including routine requestors of Part 2 records, on whether and to what extent the Department should require Part 2 programs to inform requestors when a preexisting consent exists for disclosure and the scope of such consent for disclosure. This input would be helpful as the Department considers how to facilitate covered entities' abilities to use the new permissions for TPO disclosures and related redisclosures under the Privacy Rule and Part 2. The Department also seeks comments on the extent to which Part 2 programs accept or rely on oral revocations of consent, and if so, whether and how this is documented or tracked.

§ 2.32—Notice To Accompany Disclosure (Proposed Heading)

The Department proposes 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.

The Department proposes 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

[164] *See* 82 FR 6052, 6056–6057, 6081, 6090.

[165] *See* Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE). Q15. Does Part 2 require the use of original signed consents? *https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf.*

[166] *See* Cures Act Final Rule, 85 FR 25746 (discussing ONC's adoption of requirements and standards for authentication and authorization). *See also* CMS' Interoperability and Patient Access Rule, 85 FR 25510, 25545 (stating that ''HHS is collectively working to explore standards and technical supports for data segmentation for privacy and consent management and point commenters to the ONC 21st Century Cures Act final rule for additional discussion on this. We also note that using the appropriate FHIR profiles, such as those being finalized by HHS in the ONC 21st Century Cures Act final rule . . . for API technical standards, including the SMART IG (using the OAuth 2.0 standard) and OpenID Connect as finalized at 45 CFR 170.215, can be leveraged to support this.''

[167] *See* 65 FR 82462, 82515 (December 28, 2000).

use or disclosure of such records or testimony in civil, criminal, administrative, and legislative proceedings, absent consent or a court order. The Department intends for ''proceedings'' to be understood broadly, to encompass investigations as in the existing regulation. Thus, investigative agencies should understand the continuing expectation that the requirement to seek a court order applies at the early stages of a proceeding where Part 2 records are sought to be used and disclosed.

In addition, the proposal would list exceptions to the general rule prohibiting further use or disclosure of the Part 2 records by recipients of such records, which would include an exception for covered entities, business associates, and Part 2 programs who receive Part 2 records for TPO based on a patient's consent and now may redisclose the records as permitted by the Privacy Rule. This exception also would apply to entities that received Part 2 records from a covered entity or business associate under the Privacy Rule disclosure permissions although the legal proceedings prohibition would still apply to covered entities and business associates that receive these Part 2 records. 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 concerning redisclosure permissions for covered entity, business associate, and Part 2 program recipients of Part 2 records.

The Department also proposes a change to the simplified alternative language in paragraph (a)(2) of § 2.32. The Department would add the term ''use'' to make clear that authorized uses and disclosures are prohibited by this part. The Department notes that a Part 2 program or other person holding of Part 2 records could still choose whether to adopt the more detailed revised notice or to use the simple notice.

The Department requests comment on the proposed approach to the notice to accompany disclosure, including whether the alternative simplified notice in paragraph (a)(2) is sufficient to inform recipients of Part 2 records and whether the revised notice in paragraph (a)(1) should include different elements.

§ 2.33—Uses and Disclosures Permitted With Written Consent (Proposed Heading)

Section 2.33 of 42 CFR part 2 currently permits Part 2 programs to disclose Part 2 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).

To implement sections 3221(b) and (k)(4) of the CARES Act, the Department proposes to amend the heading of this section to refer to ''Uses and disclosures permitted with written consent'' instead of solely ''disclosures.'' The Department further proposes to add ''use'' to refer to ''use or disclosure'' instead of only ''disclosure'' in paragraphs (a) and (b) and (b)(2), as modified. The Department believes these changes would align this section with proposed §§ 2.31 and 2.32 as discussed above. The Department further believes these proposals are consistent with the congressional intent expressed in 42 U.S.C. 290dd–2(b)(1), as amended by section 3221(b) of the CARES Act, which aligns Part 2 with the Privacy Rule for purposes of TPO uses and disclosures.

The Department also proposes to revise paragraph (b) by removing the list of permitted payment and health care operations uses and disclosures, adding language to paragraphs (b) and (b)(1), re-designating paragraph (2) as paragraph (3), and adding a new paragraph (b)(2).[168] Specifically, the Department proposes to create two categories of redisclosure permissions. The first category would apply to Part 2 programs, covered entities, and business associates that have received a Part 2 record with consent for TPO and would permit the recipient to redisclose the records for uses and disclosures as permitted by the Privacy Rule, subject to the limitations of proposed subpart E of Part 2 pertaining to legal proceedings. The second category 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 category 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. The Department has not proposed to define the terms ''contractors, subcontractors, and legal representatives'' because it does not intend to change the accepted understanding of these business relationships between the recipient of Part 2 records under a written patient consent and the entities that it uses to carry out its business activities. The Department requests comment on whether it would be helpful to define these terms and, if so, what definitions would appropriately retain the existing accepted understanding of the business relationships.

The proposed changes would implement section 3221 of the CARES Act by permitting covered entities and business associates to use and redisclose Part 2 records in accordance with the standards that apply to PHI in the Privacy Rule and permitting Part 2 programs to use, disclose, and redisclose Part 2 records for TPO purposes when the records are obtained under a written consent given once for all future TPO uses and disclosures. The expanded ability to use and disclose Part 2 records would facilitate greater integration of SUD treatment information with other PHI. The Department believes this change would improve communication and care coordination between providers and with other elements of the health care system, such as the ability of payers to share SUD treatment claims information with alternative payment model providers for population health management, and enhance the ability to comprehensively diagnose and treat the whole patient. It would also facilitate the exchange of Part 2 records between Part 2 programs and reduce burdens on such exchanges by allowing a written consent to be given once for all future TPO uses and disclosures. The Department supports the sharing of Part 2 records among health care entities and patients for continuity of care purposes and has proposed to align the Part 2 consent requirements and disclosure permissions with the Privacy Rule to the extent possible for such purposes within the legal authority granted by Congress.

Only redisclosures for legal proceedings by covered entities or business associates would be subject to the more stringent Part 2 restrictions, as discussed below in relation to §§ 2.64 and 2.65. Finally, the Department proposes to exclude covered entities and business associates from the requirements of paragraph (c) because they are already subject to the Privacy Rule requirements for business associate agreements. The Department welcomes comments concerning the extent to which the proposed changes to § 2.33 would result in reduction of patient

[168] Section 3221(b) of the CARES Act is codified at 42 U.S.C. 290dd–2(b)(1)(C).

trust that their Part 2 records will be kept confidential and thus affect the ability to provide treatment to patients with SUD. The Department requests comment on how Part 2 programs and recipients of Part 2 records would identify records for which a patient has given consent for TPO uses and disclosures generally as compared to consent for one purpose or a consent limited to certain segments of Part 2 information. In addition, the Department seeks comment on the ways to increase coordination amongst not only amongst Part 2 programs or recipients of Part 2 records and providers of other healthcare services but also with the health IT developer and HIE communities to protect privacy for Part 2 records within EHRs. Finally, the Department requests comment on how the proposed revisions to § 2.33 might affect the future data segregation practices of Part 2 programs and recipients of Part 2 records.

§ 2.34—Uses and Disclosures To Prevent Multiple Enrollments (Proposed Heading)

Section 2.34 permits a Part 2 program to disclose patient records to certain central registries to prevent multiple enrollments of a patient to withdrawal management or maintenance treatment programs when conditions are met. The Department proposes to replace the phrase ''re-disclose or use'' with ''use or redisclose'' at § 2.34(b), as it relates to preventing a registry from using or redisclosing Part 2 records, to align the language of this provision with the Privacy Rule as discussed above. The Department also proposes a minor wording change to refer to ''use of information in records'' instead of just ''use of information'' to make clear that this provision relates to Part 2 records.

§ 2.35—Disclosures to Elements of the Criminal Justice System Which Have Referred Patients

Section 2.35 of 42 CFR part 2 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 proposes 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.'' As discussed above, the term ''individual'' is defined in the HIPAA Rules to refer to natural persons who are the subject of PHI,[169] while the analogous term in Part 2 for the subjects of Part 2 records is ''patient.''

To avoid potential misunderstanding due to different terminology, the Department proposes to use ''persons'' when referring to someone other than the individual patient. In conjunction with this proposed change in usage, the Department proposes to replace the Part 2 definition of ''person'' with the HIPAA regulatory definition at 45 CFR 160.103. This definition includes both natural persons and legal entities. The Department also proposes to add the phrase ''from a record'' after the term ''information'' to make clear that this section regulates ''records'', and replaces ''disclosure and use'' with ''use and disclosure'' in several places to parallel the Privacy Rule.

The Department welcomes comment on its approach to identifying ''persons'' within the criminal justice system who have referred patients to a Part 2 program, including whether the alternative term ''personnel'' would more accurately cover the circumstances under which referrals under § 2.35 are made.

Subpart D—Uses and Disclosures Without Patient Consent (Proposed Heading)

The Department proposes to modify the heading of subpart D by adding the term ''uses'' so it reads ''Uses and Disclosures Without Patient Consent'' to clarify that some of the regulated activities in this subpart—including research in § 2.52(b) (*e.g.,* conducting scientific research using patient identifying information), preparing research reports in § 2.52(b)(3), and Audit and evaluation (now proposed as ''Management audits, financial audits, and program evaluation'')—include internal uses of Part 2 records by regulated entities.

§ 2.51—Medical Emergencies

Section 2.51 of 42 CFR part 2 permits Part 2 programs to disclose patient identifying information to medical personnel in certain circumstances. In § 2.51(c)(2), the Department proposes to replace the term ''individual'' with the term ''person'' as discussed above in § 2.11, *Definitions.*

§ 2.52—Scientific Research (Proposed Heading)

Section 2.52 of 42 CFR part 2 permits Part 2 programs to disclose patient identifying information for research, without patient consent, under limited circumstances. The Department proposes to update the title of this section for consistency with the statute and to add the term ''use'' to § 2.52(a). 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. The Department proposes to change the standard in § 2.52(b)(3) to more closely align with the Privacy Rule de-identification standard. Specifically, for § 2.52(b)(3), the Department proposes changes to the text to read: ''. . . patient identifying information has been de-identified in accordance with the requirements of the 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.'' The Department requests comment on any benefits, costs, and potential unintended adverse consequences that may result from this proposed change. The Department also proposes 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.''

§ 2.53—Management Audits, Financial Audits, and Program Evaluation (Proposed Heading)

The Department proposes 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 proposes to replace several instances of the phrase ''individual or entity'' with the term ''person'', which would encompass both individuals and entities.

Section 2.53 of 42 CFR part 2 permits a Part 2 program or lawful holder to disclose patient identifying information to any 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.

There is significant overlap between activities described as ''audit and evaluation'' in § 2.53 and health care operations as defined in the Privacy

[169] *See* 45 CFR 160.103 (definition of ''Individual'').

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 Privacy Rule, as cited below:

- § 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);[170]
- § 2.53(c)(2) (reviews of appropriateness of medical care, medical necessity, and utilization of services).[171]
- § 2.53(d) (accreditation).[172]

In addition, activities by individuals and entities conducting Medicare, Medicaid, and CHIP audits or evaluations described at § 2.53(e) parallel those defined as health oversight activities in the Privacy Rule at 45 CFR 164.512(d)(1). Part 2 programs and lawful holders making disclosures to these individuals and entities 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).[173]

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.[174] Covered entities, business associates, and Part 2 programs are further permitted to redisclose the same information in accordance with the Privacy Rule. As the Department has noted throughout this NPRM, these new disclosure pathways are permissive, not required.

To implement the new TPO permission that includes the ability of such entities to use or disclose Part 2 records for health care operations with a general consent, the Department proposes 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 provision would clarify that Part 2 programs, covered entities, and business associates are permitted to disclose Part 2 records pursuant to a consent for all future TPO uses and disclosures when a requesting entity is seeking records for activities described in paragraphs (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 Privacy Rule. Thus, if an auditing entity is a Part 2 program, covered entity, or business associate that has obtained 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 therein.

The CARES Act does not expressly address § 2.53; however, there is overlap between the audit and evaluation activities contemplated in § 2.53 and some activities defined as health care operations and health oversight activities in the Privacy Rule. The Department has consistently subjected its health oversight uses and disclosures to the requirements of § 2.53, and it does not believe that Congress intended differently when it amended section 290dd–2(b)(1)(B) of 42 U.S.C.

As under the existing regulation, a person performing applicable audit and evaluation activities may rely instead on patient consent for health care operations as a means of obtaining the needed records. The Department believes that in many instances this would not be feasible because it would require tracking and segregating records with consent from those without consent, and would reduce the overall number of records available for auditing and evaluation. However, the Department requests comment on whether the new redisclosure permission for Part 2 programs, covered entities, and business associates may create incentives for such recipients to rely on patient consent more frequently when performing audit and evaluation of records made available by Part 2 programs. Proposed paragraph (h) 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.

The Department proposes this approach because it believes there is no basis to fully align the Part 2 audit and evaluation provisions with the Privacy Rule, given that the CARES Act consent provisions specifically incorporated only uses and disclosures for TPO purposes, not for health oversight activities. The Department requests comment on this interpretation and any anticipated benefits or costs of treating some audit and evaluation activities under Part 2 differently than others based on whether the activities would constitute health care operations or health oversight activities.

§ 2.54—Disclosures for Public Health (Proposed Heading)

The existing Part 2 regulations do not permit the disclosure of Part 2 records for public health purposes. The CARES Act, section 3221(c), 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. Therefore, the Department proposes to add § 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). This change is proposed in conjunction with the Department's proposed definitions for public health authority as described

[170] *See, e.g.,* 45 CFR 164.501 (definition of ''Health care operations'', paragraph 5).

[171] *See, e.g.,* 45 CFR 164.501 (definition of ''Health care operations'', paragraph 1).

[172] *See, e.g.,* 45 CFR 164.501 (definition of ''Health care operations'', paragraph 2).

[173] *See* 42 CFR 2.53(e)(6).

[174] Codified at 42 U.S.C. 290dd–2(b)(1)(B).

above. Further, 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.

The Department requests comment on any benefits or costs that may result from this proposed change.

Subpart E—Court Orders Authorizing Use and Disclosure (Proposed Heading)

The Department proposes to modify the heading of subpart E to reflect changes made to the provisions of this subpart related to the use and disclosure of Part 2 records in proceedings consistent with 42 U.S.C. 290dd–2(b) and (2)(c), as amended by the section 3221(b) and (e) of the CARES Act.

§ 2.61—Legal Effect of Order

Current § 2.61 includes the requirement that beyond a court order, a subpoena must be issued to a Part 2 program in order to compel disclosure of Part 2 records. In addition to non-substantive wording edits reflected in the proposed regulatory text, the Department proposes to add the word ''use'' to paragraphs (a), (b)(1) and (b)(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 believes this approach is consistent with the CARES Act amendments to 42 U.S.C. 290dd–2.

§ 2.62—Order Not Applicable to Records Disclosed Without Consent to Researchers, Auditors and Evaluators

Currently, § 2.62 provides that a court order may not authorize qualified personnel who have received patient identifying information without consent for research, audit, or evaluation, to disclose the information or use it to conduct a criminal investigation of the patient. In addition to wording changes to improve readability, and reordering the phrase ''disclosure and use'' to ''use and disclosure'' for the same reasons described in other sections, the Department proposes to replace the term ''qualified personnel'' with a description of who falls within the term. 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 proposes to refer instead to ''persons who meet the criteria specified in § 2.52(a)(1)(i)–(iii) of this part,'' and later in the paragraph to ''such persons.''

§ 2.63—Confidential Communications

Section 2.63(a) of 42 CFR part 2 currently 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 a threat of serious bodily injury; (2) to prosecute the patient for a serious crime; or (3) in connection with litigation or an administrative proceeding in which the patient introduces their own Part 2 records. Paragraph (c) of 42 U.S.C. 290dd–2, as amended by section 3221(e) CARES Act, provides that Part 2 records may be disclosed in noncriminal legal proceedings only with patient consent or a court order, and added civil litigation and administrative proceedings to the list of proceedings for which Part 2 records cannot be used or disclosed by a government authority against a patient, absent a court order. To implement the changes to 42 U.S.C. 290dd–2, the Department proposes 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 in Part 2 records when the patient opens the door by introducing their records or testimony that relays information in their records as evidence.

§ 2.64—Procedures and Criteria for Orders Authorizing Uses and Disclosures for Noncriminal Purposes (Proposed Heading)

Section 2.64 of 42 CFR part 2 governs court orders authorizing the disclosure of patient records for noncriminal investigations or prosecutions. Paragraph (a) of this section provides that any person with a legally recognized interest may apply for a court order authorizing the disclosure of patient records in noncriminal proceedings, and such person may file the application separately or as part of a pending civil action in which they assert the evidentiary need for the records. A court order under this section (or any section within subpart E) would be limited to the circumstances specified in § 2.63, discussed above. Section 3221(e) of the CARES Act expanded privacy protections by prohibiting the use of Part 2 records for these purposes, or disclosure or use of testimony relaying the contents of a patient's records. To implement this change, the Department proposes to modify the heading, paragraph (a), and paragraph (e) to include use, not only disclosure, of Part 2 records, and the use or disclosure of testimony relaying the information in such records.

The Department further proposes to modify § 2.64(a) by adding administrative, or legislative proceedings to the types of noncriminal proceedings for which a use or disclosure of Part 2 records must be authorized by a court order, absent patient consent or the application of § 2.53(e). Section 290dd–2(c) of 42 U.S.C., as amended, requires a court order, even when the disclosure or use is sought in an administrative, or legislative proceeding. Thus, when disclosure or use of Part 2 records or testimony relaying information in a record is sought in a non-judicial proceeding, the application would be filed separately in court.

Paragraph (e) of § 2.64 sets forth limitations for court orders authorizing the disclosure of patient records in noncriminal proceedings, limiting such disclosures to the portions of the patient's record that are essential to fulfill the purpose of the order. The Department proposes to add the word ''only'' to clarify the extent of the limitation. The disclosure must also be limited to those persons whose need for the information is the basis for the order and must include necessary measures to limit the use or disclosure.

The Department also proposes to modify subparagraphs (e)(1) through (e)(3) to include the use of patient records and the use or disclosure of testimony relaying the information in patient records. The Department proposes these modifications to align with 42 U.S.C. 290dd–2(c)(1) through (c)(3), as amended by section 3221(e) of the CARES Act (expanding privacy protection by prohibiting the use or disclosure of patient records or testimony relaying the contents of a patient's records).

§ 2.65—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Criminally Investigate or Prosecute Patients (Proposed Heading)

Section 2.65 of 42 CFR part 2 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 investigative or prosecutorial activities with respect to the enforcement of criminal laws, may apply for a court order authorizing the disclosure of Part 2 records to

criminally investigate or prosecute a patient of a Part 2 program. The Department proposes the change, as discussed above, to refer to ''use and disclosure'' throughout this section instead of ''disclosure and use.''

Parallel to the proposed changes to § 2.64, discussed above, the Department proposes to modify § 2.65(a) to include the use and disclosure of testimony relaying the information in patient records because the current provision is limited to disclosure of records and does not address the CARES Act expanded privacy protection which also prohibits the use or disclosure of testimony relaying the contents of a patient's records. The Department further proposes to modify § 2.65(a) to add administrative, and legislative criminal proceedings to the criminal proceedings for which the use or disclosure of Part 2 patient records may be authorized by a court order, consistent with the CARES Act. In addition to criminal prosecutions brought as part of the judicial process, criminal investigations may be carried out by executive agencies and legislative bodies and the CARES Act has widened the confidentiality protections for patients in all of these forums where there may be a risk of exposure and liability.

Subparagraph (d) of § 2.65 sets forth criteria for the issuance of a court order authorizing the disclosure and use of patient records to conduct a criminal investigation or prosecution of a patient. Specifically, § 2.65(d)(2) requires a reasonable likelihood that the records would disclose information of substantial value in the investigation or prosecution.

The Department proposes to modify §§ 2.65(d) and (d)(2) in a manner similar to proposed § 2.65(a), discussed above, to include the use or disclosure of testimony relaying the information in Part 2 records. Under the proposed modification, the criteria in § 2.65(d) would apply to court orders authorizing not only the use and disclosure of Part 2 records, but also the use and disclosure of testimony relaying the information in those records, consistent with 42 U.S.C. 290dd–2(c), as amended section 3221(c) of the CARES Act.

Subparagraph (e) of § 2.65 sets forth requirements for the content of a court order authorizing the use or disclosure of patient records for the criminal investigation or prosecution of the patient. Specifically, § 2.65(e)(1) requires that such order must limit the use or disclosure to those parts of the patient's record as are essential to fulfill the objective of the order. Section 2.65(e)(2) requires that the order limit the 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 to investigation and prosecution of the extremely serious crime or suspected crime specified in the application. The existing rule, at § 2.63(1) and (2), specifies that the type of crime for which an order 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.'' [175] Thus, the use of an illegal substance does not in itself constitute an extremely serious crime.

The Department proposes to modify §§ 2.65(e) and (e)(1) through (e)(2) in a manner similar to §§ 2.65(a) and 2.65(d) and (d)(2), discussed above, to include the use and disclosure of testimony relaying the information in patient records. The proposed modification would apply the same limitations on a court order authorizing the use or disclosure of a patient's records to court orders authorizing not only the use or disclosure of testimony relaying the information in those records. The proposed modification to § 2.65(e)(1) would limit uses and disclosures to those parts of a patient's records or testimony relaying the information in those records which are essential to fulfill the objective of the order. Likewise, the proposed modification to § 2.65(e)(2) would limit disclosures 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 or suspected crime specified in the application and as limited by § 2.63.

The above-noted proposed modifications to §§ 2.65(d) and (d)(2), 2.65(e), and 2.65(e)(1) and (e)(2), each would add the use and disclosure of testimony relaying the information in patient records to the protections already afforded Part 2 records under the regulations.

§ 2.66—Procedures and Criteria for Orders Authorizing Use and Disclosure of Records To Investigate or Prosecute a Part 2 Program or Person Holding the Records (Proposed Heading)

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 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.

The Department proposes 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. Specifically, the Department would require an investigative agency (other than one proceeding under § 2.53(e)) that discovers in good faith that it has obtained Part 2 records to secure the records according to § 2.16 and cease using or disclosing them until it obtains a court order authorizing the use and disclosure of the records and any records later obtained, within a reasonable period of time, but not more than 120 days after discovering it received the records. 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 proposes 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 proposes to reorganize paragraph (c) by expressly incorporating the provisions from § 2.64(d) that would require an applicant to show a court the good cause requirement and criteria, 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).

The Department proposes to replace the phrase ''disclosure and use'' with ''use and disclosure'' to align the language of this section with the Privacy

[175] 42 CFR 2.65.

Rule in paragraphs (a) through (d). The Department also proposes minor wording changes to improve readability, viewable in proposed regulatory text.

§ 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

Current § 2.67 authorizes the placement of an undercover agent in a Part 2 program as an employee or patient by law enforcement or 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.

The Department proposes to 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 proposes to create a new paragraph (c)(4) addressing investigative agencies' belated applications for a court order authorizing placement of an undercover informant or agent to investigate a Part 2 program or its employees. The 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.

Finally, the Department proposes to replace the phrase ''law enforcement or prosecutorial'' with ''investigative'' in paragraph (a) and to add the words ''using or'' in front of ''disclosing'' in paragraph (d)(3) of this section and ''and disclosure'' after the term ''use'' in paragraph (e) of this section to implement 42 U.S.C. 290dd–2(c), as amended by section 3221(e) of the CARES Act, which prohibits the use or disclosure of Part 2 records in these circumstances.

§ 2.68—Report to the Secretary (Proposed Heading)

The Department proposes to create a new § 2.68 to require investigative agencies to file an annual report with the Secretary of the applications filed for court orders after use or disclosure of records in an investigation or prosecution of a 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 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 proposes that such reports would be due within 60 days following the end of the calendar year.

Request for Comments

The Department requests public comment on all aspects of the proposed amendments to the regulations at 42 CFR part 2, Confidentiality of Substance Use Disorder Patient Records (Part 2), and 45 CFR 164.520, Notice of Privacy Practices for Protected Health Information, and on the specific questions below. The Department welcomes public comment on any benefits or drawbacks of the proposed amendments set forth above in this proposed rule.

1. § 2.2 Purpose and Effect. The Department requests comment on whether the Department's proposals adding the terms ''use'' or ''uses'' to existing regulatory text that currently only state ''disclose'' or ''disclosure,'' would substantively expand the scope of the applicable requirements and prohibitions in a manner not intended. The Department seeks input and specific examples of where the proposed insertion of new terms could result in any unintended adverse consequences for regulated entities.

2. § 2.3 Civil and Criminal Penalties for Violations. The Department requests comment on its proposals at § 2.3(b) to create a limitation on civil or criminal liability for persons acting on behalf of investigative agencies if they unknowingly receive Part 2 records while investigating a program or other person holding Part 2 records without first obtaining the requisite court order, and on the proposed conditions to qualify for the limitation. Specifically, the Department requests comment on the potential impact on patient privacy and access to SUD treatment if investigative agencies can utilize a safe harbor when they unknowingly are in receipt of Part 2 records after first checking whether the program actually provides SUD services. Additionally, the Department requests comment on whether the listed activities should be the only ways an investigative agency may establish reasonable diligence. If there should be additional ways, what should they be and should they be included in regulatory text as an exclusive list?

3. § 2.11 Definitions.

Business associate. The Department solicits comment on the proposal to adopt the definition of ''business associate'' that is used in the HIPAA Privacy Rule.

Health care operations. The Department requests comment on the proposed definition of ''health care operations'', including the proposed approach in the consent requirements to offer an opt-in for fundraising, but not for de-identification and creating a designated record set.

Intermediary. The Department requests comment on the proposed definition of intermediary and whether, in light of the new permission to disclose records for TPO based on a single prior consent, the requirements for an intermediary should be retained or removed.

Investigative agency. The Department requests comment on the proposed definition of ''investigative agency'' and any concerns about including local agencies in the term, such as lack of uniform procedures, inconsistency across a state, or examples of local investigative agencies involvement in investigating Part 2 programs. The Department also requests comment on whether to interpret state (or local, if it is added) to include Tribal agencies or whether to expressly include Tribal agencies within the regulatory definition. The existing Part 2 regulation does not reference the term ''Tribal.''

Lawful holder. Additionally, the Department requests comment on whether a definition of ''lawful holder'' is needed to properly enforce § 2.16 as discussed above and in the regulatory alternatives considered. The Department also requests comment on whether, with respect to § 2.33, there are types of recipients of Part 2 records by way of a consent that should be excluded from a definition of ''lawful holder''.

Personal representative. With respect to persons who are authorized to make health care decisions on behalf of a minor, a patient who lacks capacity to make their own decisions, or a patient who is deceased, the Department requests comment on any benefits or drawbacks of adopting the Privacy Rule term ''personal representative,'' and the description of the term in 45 CFR 164.502(g)(2), as a defined term within this part. If adopted, this term would replace the phrase ''guardian or other persons authorized under state law to act on the patient's behalf'' and ''executor, administrator, or other personal representative appointed under applicable state law.''

Records. With respect to the consideration of newly defining SUD counseling notes that would be part of a record, the Department requests comment on the benefits and burdens of adopting such a definition, similar to

the psychotherapy notes provision under HIPAA. Additionally, the Department requests comment on the scope of SUD personnel who could potentially create SUD counseling notes and utilize the additional patient privacy protections they afford and whether a regulatory definition for SUD professional should be created.

Use. With respect to the proposed definition of ''use'', the Department requests comment on whether to retain the specific reference to the use of records in certain proceedings against the patient, addressed at §§ 2.61–2.67, or whether it would be clearer to adopt only the definition of the term ''use'' from the HIPAA Rules at 45 CFR 160.103.

4. § 2.16 Security for records and notification of breaches. The Department requests public comment regarding the estimated burden for Part 2 programs that are not covered entities to comply with the proposed breach notification requirements. The Department also requests comment regarding the application of the Privacy Rule de-identification standard to rendering Part 2 records non-identifiable, as provided in the proposed modifications to § 2.16(a)(1)(v) and (a)(2)(iv), including any unintended adverse consequences that may result from these proposed changes. The Department requests comment regarding whether the Security Rule or similar requirements should apply to Part 2 programs that maintain electronic records but are not covered entities in the same manner as the Security Rule applies to covered entities and business associates. The Department requests comment on whether breach notification requirements that apply to business associates pursuant to the Privacy Rule should apply to QSOs as they are similarly situated. In addition, the Department requests comments from Part 2 programs that are not covered entities on whether they look to the HIPAA Security Rule generally for guidance on protecting electronic Part 2 records or otherwise voluntarily attempt to follow the requirements of the Security Rule. For any programs that may do so, the Department requests comment on what their experience has been, including any implementation costs. Finally, the Department requests comment on 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.

5. § 2.22 Notice to patients of Federal confidentiality requirements and 45 CFR 164.520 Notice of privacy practices for protected health information. The Department requests comment on ways to make the proposed notices more easily understandable, including examples of possible approaches, such as requiring the document to be at a particular reading grade level, maximum number of pages, or other suggestions. The Department specifically requests comment from legal, clinical, privacy, and civil rights experts on this matter.

6. § 2.24 Requirements for intermediaries. The Department solicits comment on the proposed reorganization and clarification of requirements for entities that facilitate health information exchange and whether there is a continued need for these requirements in light of the accounting of disclosures proposed in § 2.25. Specifically, the Department solicits comment on how Part 2 programs have been implementing the existing requirements for intermediaries in § 2.13(d) and § 2.31(a)(4)(ii) and examples of how those requirements have affected the ability of Part 2 programs to utilize HIEs.

7. § 2.25 Accounting of disclosures. The Department requests comment on the proposals to add a requirement for an accounting of disclosures for non-TPO disclosures and an accounting of disclosures through an electronic health record for TPO. The Department welcomes data from Part 2 programs that are also covered entities on the number and type of requests for an accounting of disclosures of PHI received annually, whether and how frequently they receive requests for an accounting of disclosures for TPO, and to what extent such covered entities are choosing to provide individuals with an accounting of TPO disclosures made through an electronic health record based on the HITECH Act statutory requirement, even absent an implementing regulation. The Department also welcomes comment on the provider burden and costs to respond to a request for an accounting for both TPO disclosures and non-TPO disclosures.

8. § 2.26 Right to request privacy protection for records. The Department requests comment and data on the extent to which covered entities and Part 2 programs receive requests from patients to restrict disclosures of patient identifying information for TPO purposes, how entities and programs track such requests, and the procedures and mechanisms used to comply with patient requests to which they have agreed or that they are otherwise required to comply with by law.

9. § 2.31 Consent requirements. The Department requests comments on its proposals that would implement changes to § 2.31. Specifically, the Department requests comment on whether there are other changes that it should make to further align § 2.31 with the Privacy Rule using its general regulatory authority in section 3221(i)(1) of the CARES Act ''to make such revisions to regulations as may be necessary for implementing and enforcements the amendments.'' For example, the Department requests comment on the extent to which Part 2 programs segment out SUD treatment records considered ''SUD counseling notes.'' The Department requests comment on whether to propose special protection for SUD counseling notes to add a layer of regulatory protection that equates to the protection granted to psychotherapy notes in the Privacy Rule by requiring a separate written consent for their disclosure.[176]

The Department also solicits comment on the proposed changes to the consent requirements for entities that facilitate health information exchanges (*i.e.,* intermediaries), particularly how they would affect the implementation of proposed changes to consent for TPO. The Department requests comment on whether, and to what extent, Part 2 programs currently act on an oral revocation of consent, and if so, whether and how this is documented or tracked.

10. § 2.32 Notice to accompany disclosure. The Department welcomes comment from Part 2 programs that are covered entities, and recipients of Part 2 records that are covered entities or business associates, on whether and how the proposed changes to the redisclosure permissions in § 2.32 are likely to reduce data segregation and positively affect the ability to provide treatment to patients with SUD and perform other beneficial activities. Specifically, the Department seeks comment on whether the proposed changes alone would be sufficient to implement section 3221 of the CARES Act, or whether different or additional modifications to Part 2 would be more effective to promote integration of Part 2 records with PHI, reduce stigma for patients with SUD, and improve access

[176] *See e.g.,* 45 CFR 164.508(a)(2) requiring a covered entity to obtain written authorization prior to using or disclosing psychotherapy notes, subject to certain exceptions, and prohibiting the combining of an authorization to disclose psychotherapy notes with an authorization to disclose other types of PHI.

to SUD treatment while maintaining the confidentiality of Part 2 records as required by 42 U.S.C. 290dd–2.

11. § 2.33 Uses and disclosures permitted with written consent. The Department requests comment on whether or how recipients of Part 2 records are informed that the records have been disclosed based on patient consent and the scope of the consent that is provided. Specifically, the Department welcomes data on how Part 2 programs and recipients of Part 2 records communicate information about the purpose of a disclosure or set of disclosures and the extent of the information communicated about the purpose or the scope of the disclosure permission, authorization, or mandate. Should the Department consider requiring Part 2 programs to provide a copy of the written patient consent when disclosing records? Should the Department consider requiring Part 2 programs, covered entities, and business associates to retain a copy of the written patient consent for a minimum period of time so that they can provide documentation of the consent to future recipients, or to the Secretary for purposes of investigating compliance with Part 2? Are programs already doing this? To what extent would such requirements be useful to recipients of Part 2 records or impose a burden on programs? Additionally, should the Department require 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? The Department also welcomes comments on the potential unintended negative effects on confidentiality and privacy from the combined application of the proposed disclosure permissions for TPO with consent under § 2.33, and the removal of § 2.53 protections for audit and evaluation activities that fall within the definition of health care operations, and suggested regulatory approaches.

12. § 2.52 Scientific research. The Department requests public comment on whether any Part 2 programs conduct research using their own Part 2 records. The Department also requests public comment regarding the application of the HIPAA de-identification standard to Part 2 records disclosed for research, as provided in the proposed modifications to § 2.52(a)(3), including any unintended adverse consequences that may result from this proposed change.

13. § 2.53 Management audits, financial audits, and program evaluation. The Department requests comment on its proposal to acknowledge within this section the applicable permission for use and disclosure of records for health care operations purposes based on written consent of the patient for all future uses and disclosures for TPO and the permission for the third party conducting such audit or evaluation activities to redisclose the records as permitted by the HIPAA Privacy Rule if the third-party recipient is a Part 2 program, covered entity, or business associate that is not acting as a health oversight agency.

14. Section 2.54 Disclosures for public health. The Department requests comment on its proposal to permit disclosures only of de-identified records for public health purposes without patient consent.

15. Subpart E. The Department seeks comment on the set of proposals in §§ 2.3, 2.66, 2.67, and 2.68 to create a limitation on civil and criminal liability for investigative agencies that in good faith discover they have received Part 2 records before obtaining the required court order in the course of investigating or prosecuting a program, and the related requirement for agencies that make use of these provisions to submit a report to the Secretary.

Public Participation

The Department seeks comment on all issues raised by the proposed regulation, including any unintended adverse consequences. Because of the large number of public comments normally received on **Federal Register** documents, the Department is not able to acknowledge or respond to them individually. In developing the final rule, the Department will consider all comments that are received by the date and time specified in the **DATES** section of the Preamble.

Because mailed comments may be subject to security delays due to security procedures, please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Any attachments submitted with electronic comments on *www.regulations.gov* should be in Microsoft Word or Portable Document Format (PDF). Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Regulatory Impact Analysis

The Department has examined the impact of the proposed rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (October 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (August 10, 1999); Executive Order 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); Executive Order 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 of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995).

A. Executive Orders 12866 and 13563 and Related Executive Orders on Regulatory Review

Executive Order 12866 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). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in, Executive Order 12866.

This proposed rule is partially regulatory and partially deregulatory. The Department estimates that the effects of the proposed requirements for Part 2 programs would result in new costs of $19,364,667 within 12 months of implementing the final rule. The Department estimates these first-year costs would be partially offset by $12,755,378 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) ($9.8 million); reductions in the need for covered entities, business associates, and Part 2 programs to obtain written patient consent for redisclosures ($2.5 million); and reductions in capital expenses for printing consent forms ($0.5 million). This is followed by net savings of $10,240,622 annually in years two through five, resulting from a continuation of first-year cost saving of $12.8 million per year, minus the estimated annual costs of $2.5 million primarily attributable to compliance with breach notification requirements. This results in overall net cost savings of $34,353,198 over 5 years for changes

to 42 CFR part 2. In addition, the Department estimates that changes to 45 CFR 164.520 would result in new nonrecurring costs for covered entities that receive or maintain Part 2 records in the amount of $44,935,225. Combined, the proposed regulatory changes to Part 2 and the Privacy Rule would result in estimated total costs of $64,299,891 in the first year (approximately $19 million from Part 2 programs and $45 million from 45 CFR 164.520), followed by $2,514,756 of recurring annual costs in years two through five (from Part 2 programs), for a total of $74,358,914. This would be offset by an estimated annual savings of $12,755,378 for a total of $63,776,888 over five years. The combined result would be a net cost of $51,544,514 in the first year following the rule's effective date, followed by annual net savings of $10,240,622, resulting in 5-year net cost of $10,582,027 for HIPAA covered entities and Part 2 programs.

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. As a result of the economic impact, the Office of Management and Budget (OMB) has determined that this proposed rule is not an economically significant regulatory action within the meaning of section (3)(f)(1) of E.O. 12866; however, it is a significant regulatory action because it presents novel legal and policy issues. Accordingly, OMB has reviewed this proposed rule.

The Department presents a detailed analysis below.

Summary of the Proposed Rule

This Notice of Proposed Rulemaking (NPRM) proposes to modify 42 CFR part 2 (''Part 2'') and 45 CFR 164.520 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 proposals are summarized below:

(1) § 2.1—Statutory authority for confidentiality of substance use disorder patient records.

Revise § 2.1 to more closely reflect the authority granted in 42 U.S.C. 290dd–2(g), especially with respect to court orders authorizing the disclosure of records.

(2) § 2.2—Purpose and effect.

Amend paragraph (b) of § 2.2 to reflect that § 2.3(b) compels disclosures to the Secretary that are necessary for enforcement of this rule, using language adapted from the Privacy Rule at 45 CFR 164.502(a)(2)(ii). Add a new paragraph (b)(3) to this section to prohibit any limits on a patient's right to request restrictions on use of records for treatment, payment, or health care operations (TPO) or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the Privacy Rule.

(3) § 2.3—Civil and criminal penalties for violations (proposed heading).

Amend the heading and replace title 18 U.S.C. enforcement with references to the HIPAA enforcement authorities in the Social Security Act at sections 1176 (civil enforcement, including the CMP tiers established by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and 1177 (criminal penalties),[177] as implemented in the Enforcement Rule.[178] Create a limitation on civil or criminal liability for investigative agencies that act with reasonable diligence before making a demand for records in the course of an investigation of a program or other person holding Part 2 records by taking certain steps to determine whether a provider is subject to Part 2.

(4) § 2.4—Complaints of violations. (proposed heading)

Amend the heading and insert requirements consistent with those applicable to HIPAA complaints under 45 CFR 164.530(d), (g), and (h), including: a requirement to establish a process for the Part 2 program to receive complaints, a prohibition against taking adverse action against patients who file complaints, and a prohibition against requiring individuals to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.

(5) § 2.11—Definitions.

Add new terms and definitions to align with the following statutory and regulatory HIPAA terms: *Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Payment, Person, Public health authority, Treatment, Unsecured protected health information,* and *Use.* Create new definitions for the terms *Intermediary, Investigative agency,* and *Unsecured record,* and modify the definitions of *Informant, Part 2 program director, Patient, Program, Records, Third-party payer, Treating provider relationship,* and *Qualified service organization.*

(6) § 2.12—Applicability.

Replace ''Armed Forces'' with ''Uniformed Services'' in paragraph (c)(2) of § 2.12. Incorporate 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. Add language to qualify the term third-party payer with the phrase ''as defined in this part.'' Revise paragraph (e)(4)(i) to clarify when a diagnosis it not covered by Part 2.

(7) § 2.13—Confidentiality restrictions and safeguards.

Redesignate § 2.13(d) requiring a list of disclosures as new § 2.24 and modify the text for clarity. Amend the heading to distinguish the right to a list of disclosures made by intermediaries from the proposed new right to an accounting of disclosures made by a Part 2 program.

(8) § 2.14—Minor patients.

Change the verb ''judges'' to ''determines'' to describe a program director's evaluation and decision that a minor lacks decision making capacity.

(9) § 2.15—Patients who lack capacity and deceased patients. (proposed heading)

Revise to replace outdated language and refer instead to a lack of capacity to make health care decisions and add health plans to the list of entities to which a program may disclose records without consent.

(10) § 2.16—Security for records and notification of breaches. (proposed heading)

Apply the HITECH Act breach notification provisions[179] that are currently implemented in the Breach Notification Rule to breaches of records by Part 2 programs and retitle the provision to include breach notification to implement CARES Act provisions. Modify the provision to refer to the Privacy Rule de-identification standard at 45 CFR 164.514.

(11) § 2.19—Disposition of records by discontinued programs.

Add an exception to clarify that these provisions do not apply to transfers, retrocessions, and reassumptions of Part 2 programs under the Indian Self-Determination and Education

[177] *See* Public Law 111–5, 123 Stat. 226 (February 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) to add civil and criminal penalty tiers for violations of the HIPAA Administrative Simplification provisions.

[178] *See* 45 CFR part 160.

[179] 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.

Assistance Act (ISDEAA), in order 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. Modernize the language to refer to ''non-electronic'' records and include ''paper'' records as an example of non-electronic records.

(12) § 2.22—Notice to patients of federal confidentiality requirements.

Modify the Part 2 confidentiality notice requirements (hereinafter, ''Patient Notice'') to align with the Notice of Privacy Practices (NPP) and address protections required by 42 U.S.C. 290dd–2, as amended by section 3221 of the CARES Act, for entities that create or maintain Part 2 records.

(13) § 2.23—Patient access and restrictions on use and disclosure. (proposed heading)

Add 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) § 2.24—Requirements for intermediaries (redesignated and proposed heading).

Retitle the redesignated section (to be moved from § 2.13(d)) as ''Requirements for intermediaries'' to clarify the responsibilities of recipients of records received under a consent with a general designation, such as health information exchanges, research institutions, accountable care organizations, and care management organizations.

(15) § 2.25—Accounting of disclosures (proposed heading).

Add this section to implement 42 U.S.C. 290dd–2(b)(1)(D), as amended by the section 3221 of the CARES Act, to incorporate into Part 2 the HITECH Act right to an accounting of certain disclosures of records for up to three years prior to the date the accounting is requested and add a right to an accounting of disclosures of records that mirrors the standard in the Privacy Rule at 45 CFR 164.528.

(16) § 2.26—Right to request privacy protection for records (proposed heading).

Add this 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 HITECH Act rights implemented in the Privacy Rule at 45 CFR 164.522, namely: (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. (proposed heading)

Change the heading of subpart C to ''Uses and Disclosures With Patient Consent'' 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) § 2.31—Consent requirements.

Align the content requirements for Part 2 written consent with the content requirements for a valid HIPAA authorization and clarify how recipients may be designated in a consent to use and disclose Part 2 records for TPO.

(19) § 2.32—Notice to accompany disclosure (proposed heading).

Change the heading of this section and align 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.

(20) § 2.33—Uses and disclosures permitted with written consent (proposed heading).

To align 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, replace the provisions requiring consent for uses and disclosures for payment and certain health care operations with permission to use and disclose records for TPO based on a single consent given once for all such future uses and disclosures, until such time as the patient revokes the consent in writing. Create redisclosure permissions for two categories of recipients of Part 2 records pursuant to a written consent: (1) Permit a Part 2 program, covered entity, or business associate that receives Part 2 records pursuant to a written consent for TPO purposes to redisclose the records in any manner permitted by the Privacy Rule, except for certain legal proceedings against the patient; [180] and (2) Permit a lawful holder that is not a covered entity, business associate, or Part 2 program 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 in the consent.

(21) § 2.35—Disclosures to elements of the criminal justice system which have referred patients.

For clarity, replace ''individuals'' with ''persons'' and clarify that permitted redisclosures of information are from Part 2 records.

(22) Subpart D—Uses and Disclosures Without Patient Consent (proposed heading).

Change the heading of subpart D to ''Uses and Disclosures Without Patient Consent'' 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) § 2.51—Medical emergencies.

For clarity in § 2.51(c)(2), replace the term ''individual'' with the term ''person.''

(24) § 2.52—Scientific research (proposed heading).

Revise the heading of § 2.52 to reflect statutory language. To further align Part 2 with the Privacy Rule, replace the requirements to render Part 2 data in research reports non identifiable with the Privacy Rule's de-identification standard in 45 CFR 164.514.

(25) § 2.53—Management audits, financial audits, and program evaluation (proposed heading).

Revise the heading of § 2.53 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, add a provision to acknowledge the permission for use and disclosure of 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) § 2.54—Disclosures for public health (proposed heading).

Add a new § 2.54 to implement 42 U.S.C. 290dd–2(b)(2)(D), as amended by section 3221(c) of the CARES Act, to permit 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 (proposed heading).

Change the heading of subpart E 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) § 2.61—Legal effect of order.

Add the term ''use'' to clarify that the legal effect of a court order would include authorizing the use and

[180] *See* 42 U.S.C. 290dd–2(b)(1)(B) and (2)(c).

disclosure of records, consistent with 42 U.S.C. 290dd–2(b) and (c), as amended by section 3221(e) of the CARES Act.

(29) § 2.62—Order not applicable to records disclosed without consent to researchers, auditors, and evaluators.

For clarity, replace the term ''qualified personnel'' with a reference to the criteria that define such persons.

(30) § 2.63—Confidential communications.

Revise paragraph (c) 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.

(31) § 2.64—Procedures and criteria for orders authorizing uses and disclosures for noncriminal purposes (proposed heading).

Expand the types of forums where restrictions on use and disclosure of records in civil proceedings against patients apply [181] to expressly include administrative and legislative proceedings and also restrict the use of testimony conveying information in a record in civil proceedings against patients, absent consent or a court order. Add the term ''uses'' to the heading and in this section to align it with current statutory authority.

(32) § 2.65—Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients (proposed heading).

Expand the types of forums where restrictions on uses and disclosure of records in criminal proceedings against patients apply [182] to expressly include administrative and legislative proceedings and also restrict the use of testimony conveying information in a Part 2 record in criminal legal proceedings against patients, absent consent or a court order.

(33) § 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 heading)

Create requirements for investigative agencies to follow in the event they discover in good faith that they received Part 2 records before seeking a court order as required under § 2.66.

(34) § 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.

Add new 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).

(35) § 2.68—Report to the Secretary (proposed heading).

Create new requirements 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 and § 2.67.

(36) 45 CFR 164.520—Notice of privacy practices for protected health information.

Revise 45 CFR 164.520 to implement updates to the NPP to address Part 2 confidentiality requirements, as required by section 3221(i)(2) of the CARES Act.

The proposed changes to Part 2 and 45 CFR 164.520 would create some estimated costs, and numerous and substantial estimated cost savings and anticipated benefits that the Department is unable to quantify but are described in depth below. These include improving the integration of SUD treatment with that of other health care by facilitating the integration of SUD treatment records with other medical records, reductions in paperwork for providers, and regulatory certainty.

The Department estimates that the first-year costs for Part 2 programs will total approximately $19 million. These first-year costs are attributable to Part 2 programs training workforce members on the revised requirements ($12.4 million); capital expenses ($0.8 million); compliance with breach notification requirements ($1.5 million); updating Patient Notices and NPPs ($2.4 million); updating consent forms ($1.5 million); updating the notice to accompany disclosures ($0.6 million). It also includes nominal costs for responding to requests for privacy protection, providing accounting of disclosures, and $25,795 for investigative agencies to file reports to the Secretary. For years 2 through 5, the estimated annual costs of $2.5 million are primarily attributable to compliance with breach notification requirements and related capital expenses. Additionally, the Department estimates nonrecurring costs of $45 million for covered entities that receive or maintain Part 2 records due to updating the HIPAA NPP under 45 CFR 164.520.

The Department estimates annual cost savings of $12.8 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 ($9.8 million), reductions in the need for covered entities and business associates to obtain written patient consent for redisclosures ($2.5 million), and reductions in capital expenses for printing consent forms ($0.5 million).[183]

The Department estimates net costs for Part 2 programs totaling approximately $6.6 million in the first year followed by net savings of approximately $10 million annually in years 2 through 5, resulting in overall net cost savings of approximately $34 million over 5 years.

TABLE 1a—PART 2 ESTIMATED 5-YEAR COSTS AND COST-SAVINGS, UNDISCOUNTED, IN MILLIONS

Total Part 2 costs and cost-savings						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs:						
Total, Costs	$19	$3	$3	$3	$3	$29
Cost-Savings:						
Total, Cost-savings	13	13	13	13	13	64
Net (negative = savings)	7	(10)	(10)	(10)	(10)	(34)

[181] *See* 42 CFR part 2, subpart E.

[182] *Id.*

[183] Totals in this Regulatory Impact Analysis may not add up due to showing rounded numbers in the tables.

TABLE 1b—ESTIMATED PART 2 AND HIPAA 5-YEAR COSTS AND COST-SAVINGS, UNDISCOUNTED, IN MILLIONS

Total regulatory costs and cost-savings						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Costs:						
Total, Costs	$64	$3	$3	$3	$3	$74
Cost-Savings:						
Total, Cost-savings	13	13	13	13	13	64
Net (negative = savings)	52	(10)	(10)	(10)	(10)	11

2. Need for the Proposed 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.[184] With this NPRM, the Department proposes changes to Part 2 and 45 CFR 164.522 to implement section 3221 of the CARES Act, increase clarity, and decrease compliance burdens for regulated entities. The Department believes the proposed changes would reduce data segmentation within entities subject to the regulatory requirements promulgated under both HIPAA and Part 2.

Significant differences in the permitted uses and disclosures of Part 2 records and protected health information (PHI) as defined under the Privacy Rule contribute to ongoing operational compliance challenges. For example, currently, entities subject to Part 2 must obtain specific written consent for most uses and disclosures of Part 2 records, including for TPO, while the 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 Rules but not Part 2).[185]

In addition, once PHI is disclosed to an entity not covered by HIPAA it is no longer protected by the HIPAA Rules. 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.[186] [187] 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.[188] 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.[189] Many stakeholders have urged the Department to take action to eliminate the need for such data segmentation,[190] and the Department believes its proposals will reduce, but not completely eliminate, the need for data segmentation or tracking.

3. Cost-Benefit Analysis

Overview and Methodology

In comparison to the estimated number of HIPAA covered entities (774,331 [191]) the estimated number of Part 2 program is very small (16,066 [192]) or just 2 percent of the number of covered entities. Because the number of Part 2 programs is so small, the Department includes the entire estimated number of Part 2 programs when estimating the projected costs and cost savings of the proposals in this NPRM, even though a percentage of Part 2 programs are already complying with HIPAA requirements because they are subject to both Part 2 and HIPAA. The Department requests comment on this approach and data on the number or proportion of Part 2 programs that are also HIPAA covered entities.

This regulatory impact analysis (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'') [193] and uses an updated statistic from that source. The NPRM

[184] 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.

[185] 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.

[186] *See* 42 CFR 2.12(d)(2)(i)(C).

[187] ''*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. The term does not include 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.'' 42 CFR 2.11. *See also* definition of ''Disclose'': ''[T]o communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.'' 42 CFR 2.11.

[188] *See* 42 CFR 2.12(d)(2)(ii).

[189] McCarty, D., Rieckmann, T., Baker, R.L., & McConnell, K.J. (2017). ''The Perceived Impact of 42 CFR part 2 on Coordination and Integration of Care: A Qualitative Analysis.'' Psychiatric Services (Washington, DC), 68(3), 245–249, *https://doi.org/10.1176/appi.ps.201600138*).

[190] 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 federally qualified health centers and other integrated settings in which SUD treatment may be provided. *See also* public comments expressed and summarized in 85 FR 42986, *https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records; and see https://aahd.us/wp-content/uploads/2021/01/PartnershipRecommendationsforNextPart2-uleLtrtoNomineeBecerra_01082021.pdf.*

[191] *See* Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6498 (January 21. 2021).

[192] *See* Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N–SSATS): 2020. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021, *https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.*

[193] 85 FR 42986 (July 15, 2020).

also adopts the estimated number of covered entities used in the OCR's 2021 ICR for the Privacy Rule NPRM (''2021 HIPAA ICR''), as well as its cost assumptions for many requirements of the HIPAA Rules, including breach notification activities.

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 OCR and SAMHSA for similar regulatory requirements were developed based on different methodologies, resulting in significantly different fiscal projections for some required activities. This RIA adopts OCR's approach for those projected costs and cost savings.

In addition to the quantitative analyses of the effects of the proposed 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 proposed rule. The Department requests comment on the estimates, assumptions, and analyses contained herein—and any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA.

For reasons explained more fully below, the proposed 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 $63,776,888 over 5 years based on the proposed changes. The resulting net costs over 5 years is due to first year expenses including costs for some health plans to mail an updated NPP which would be finalized as part of a comprehensive HIPAA Privacy Rule.

TABLE 2—ACCOUNTING TABLE

Accounting table of estimated benefits and costs of all proposed changes, in millions

	Year 1	Year 2	Year 3	Year 4	Year 5	Total *
Costs:						
Undiscounted	$64	$3	$3	$3	$3	$74
3% Discount	50	2	2	2	2	58
7% Discount	37	1	1	1	1	42
Cost Savings:						
Undiscounted	13	13	13	13	13	64
3% Discount	10	10	9	9	9	47
7% Discount	7	7	6	6	6	33
NET (undiscounted)						Costs $11

Non-quantified benefits and costs are described below.

* Totals may not add up due to rounding.

Baseline Assumptions

In developing its estimates of the potential costs and cost savings of the proposed regulation the Department relied substantially on recent prior estimates for modifications to this regulation [194] and the Privacy Rule [195] and associated ICRs. Specifically, the Part 2 ICR data previously approved under OMB control #0930–0092 informs the Department's estimates with respect to proposed modifications to Part 2 provisions.[196] However, for proposed Part 2 provisions that are based on provisions of the HIPAA Rules, and for proposed changes to 45 CFR 164.520, the Department relies on OCR's HIPAA regulatory ICRs previously approved under OMB control #0945–0003 and updated consistent with OCR's 2021 Privacy Rule NPRM.[197]

Because the Department lacks data to determine the percentage of Part 2 programs that are also subject to the HIPAA Rules, the Department assumes for purposes of this analysis that the proposed 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 Rules (*e.g.,* breach notification) that the Department proposes to incorporate into Part 2. Thus, this RIA likely overestimates the overall compliance burden on Part 2 programs posed by the proposals in this NPRM. In contrast, this RIA likely underestimates the cost savings of the NPRM. 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 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 NPRM's proposals. The Department requests comments on its assumptions and data to refine its estimates.

Part 2 Programs, Covered Entities, and Patient Population

The Department relies on the same source as the approved Part 2 ICR [198] 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–

[194] *See* 83 FR 239 (January 3, 2018) and 85 FR 42986 (July 15, 2020).

[195] 86 FR 6446 (January 21, 2021).

[196] 85 FR 42986 (July 15, 2020).

[197] 84 FR 51604 (September 30, 2019). *See also* 86 FR 6446 (January 21, 2021).

[198] 85 FR 42986 (July 15, 2020).

0335.[199] In the 2020 data from N–SSATS, the number of Part 2 respondents was 16,066.[200] The TEDS data for SUD treatment admissions has been updated, so the Department relies on the 2019 statistic, as shown in the table below.

TABLE 3—PART 2 PROGRAMS, COVERED ENTITIES, AND PATIENTS

Estimated number of part 2 programs	Total annual part 2 program admissions
16,066	[201] 1,864,367
Estimated number of covered entities	Total annual new patients
774,331 [202]	[203] 613,000,000

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 the table below.

TABLE 4—OCCUPATIONAL PAY RATES

Occupational pay rates [a]		
Occupation code and title		Hourly wage rate × 2 [b]
00–0000	All Occupations	$56.02
43–3021	Billing and Posting Clerks	41.10
29–0000	Healthcare Practitioners and Technical Occupations	87.60
29–9098	Health Information Technologists, Medical Registrars, Surgical Assistants, and Healthcare Practitioners and Technical Workers, All Other	59.06
15–1212	Information Security Analysts	108.92
23–1011	Lawyer	142.34
13–1111	Management Analysts	96.66
11–9111	Medical and Health Services Manager	115.22
29–2098	Medical Records Specialist	46.46
43–0000	Office and Administrative Support Occupations	41.76
11–2030	Public Relations and Fundraising Managers	127.70
21–1018	Substance Abuse, Behavioral Disorder, and Mental Health Counselors	51.44
13–1151	Training and Development Specialist	65.02
43–4171	Receptionist and Information Clerk	31.64
15–1257	Web Developer and Digital Interface Designer	91.80

[a] Bureau of Labor Statistics, U.S. Department of Labor, "*Occupational Employment and Wages*" May 2021, *https://www.bls.gov/oes/current/oes_stru.htm.*

[b] To incorporate employee benefits, these figures represent a doubling of the BLS mean hourly wage.

Qualitative Analysis of Non-Quantified Benefits and Burdens

The Department's analysis focuses on primary areas of proposed changes that are likely to have an impact on regulated entities or patients. These are proposals to establish or modify requirements with respect to: enforcement and penalties, notification of breaches, consent for uses and disclosures, Patient Notice and the NPP, notice 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 proposals, the Department believes the modifications to Part 2 that are proposed 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:

§§ 2.1–2.2, 2.4 Statutory authority and enforcement, § 2.11 Definitions, § 2.12 Applicability, § 2.13 Confidentiality restrictions and safeguards, § 2.14 Minor patients, § 2.15 Patients who lack capacity and deceased patients, § 2.17 Undercover agents and informants, § 2.19 Disposition of records by discontinued programs, § 2.20 Relationship to state laws, § 2.21 Relationship to federal statutes protecting research subjects against compulsory disclosure of their identity, § 2.23 Patient access and restrictions on use and disclosure, § 2.24 Requirements for intermediaries, § 2.34 Uses and Disclosures to prevent multiple enrollments, § 2.35 Disclosures to elements of the criminal justice system which have referred patients, § 2.52 Scientific research, §§ 2.61–2.65 Court Orders Authorizing Use and Disclosure.

The Department provides its analysis of non-quantified benefits and burdens for the primary areas of proposed regulatory change below, followed by estimates and analysis of quantified benefits and costs in section (e).

§ 2.3—Civil and criminal penalties for violations (proposed heading).

The Department proposes to create 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 would promote public safety by permitting agencies to investigate Part 2 programs and persons holding Part 2 records in good faith without risk of HIPAA/HITECH Act penalties. The liability

[199] 84 FR 787 (January 31, 2019).

[200] *See* Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N–SSATS): 2020. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021, *https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.*

[201] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2019. Admissions to and Discharges From Publicly Funded Substance Use Treatment. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021, *https://www.samhsa.gov/data/sites/default/files/reports/rpt35314/2019_TEDS_Proof.pdf.*

[202] 86 FR 6446 (January 21, 2021).

[203] *Id.*

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 proposed changes would 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 proposed § 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,[204] and keeping patient identifying information under seal [205] will provide strong and continuing protections for patient privacy while promoting public safety.

§ 2.16 Security for records and notification of breaches (proposed heading).

The Department proposes to add notification of breaches to § 2.16 so that the requirements of 45 CFR 164.400 *et seq.,* would 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.[206]

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 actions [207] will be far outweighed by the savings of avoiding identity theft.[208] Requiring Part 2 programs to provide breach notification would ensure that patients of such programs are provided the same informational protections as patients that receive other types of health care services from HIPAA covered entities.

§ 2.22 Patient Notice & 45 CFR 164.520 (NPP).

Patients, Part 2 programs, and covered entities are all likely to benefit from proposed changes to more closely align the Patient Notice and NPP regulatory requirements, which would simplify their compliance with the two regulations. The Department proposes to establish 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 NPRM.[209] These proposed changes would 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 proposal, knowledge of the right may promote trust and confidence in how their records are handled.

§ 2.25 Accounting of Disclosures (proposed heading).

Adding a requirement to account for disclosures for TPO through an electronic health record would benefit patients by increasing transparency about how their records are used and disclosed for those purposes. This proposed requirement could counterbalance concerns about loss of control that patients may experience as a result of the proposed 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 would 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.

§ 2.26 Right to request privacy protection for records (proposed heading).

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 program staff, to address patients' concerns about who may see their records and 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 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.[210]

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.

§ 2.31 Consent requirements and *§ 2.33 Uses and disclosures permitted*

[204] *See* § 2.66 (requiring use of ''John Doe'').

[205] *See* §§ 2.66 and 2.67.

[206] *See* Preamble, Breach Notification for Unsecured Protected Health Information, 74 FR 42739, 42765–66 (August 24, 2009).

[207] *See* Alexandria White, ''How much does credit monitoring cost?'' CNBC (November 16, 2021), *https://www.cnbc.com/select/how-much-does-credit-monitoring-cost/.*

[208] *See* Kenneth Terrell, ''Identity Fraud Hit 42 Million People in 2021,'' AARP (April 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.*

[209] *See* Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446 (January 21, 2021).

[210] National Academies of Sciences, Engineering, and Medicine. (2016). Ending Discrimination Against People with Mental and Substance Use Disorders: The Evidence for Stigma Change. Washington, DC: The National Academies Press. doi: 10.17226/23442, *http://www.nap.edu/23442;* U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health.* Washington, DC: HHS, November 2016.

with written consent (proposed heading).

The proposed 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). Proposed 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 Rules, 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 proposal 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. The Department seeks comment and specific data on the number and type of Part 2 programs that are also HIPAA covered entities or business associates. The Department also solicits comment and data on any concerns or questions Part 2 programs may have about how the information technology currently available to them can support implementation of either or both of these proposed provisions.

§ 2.32 Notice to accompany disclosure. (proposed heading)

The proposed revisions to the notice accompanying each disclosure of Part 2 records made with written consent would benefit patients by ensuring that recipients of Part 2 records would be on notice 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 proposed 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 would benefit from having notice language that accurately 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,'' as compared to the Privacy Rule whereby protections are limited to PHI held by a covered entity or business associate.

§ 2.53 Management audits, financial audits, and program evaluation (proposed heading).

Programs that are also covered entities would benefit from the proposed 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 Privacy Rule disclosure permissions for health care operations. This benefit would provide 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 Privacy Rule, with patient consent for TPO. This flexibility would not extend to government oversight audits and evaluations.

§ 2.54 Disclosures for public health (new provision)

The Department proposes to create a new permission to disclose de-identified records without patient consent for public health activities, consistent with statutory changes. This would benefit 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 would protect patient confidentiality because the permission is limited to disclosure of de-identified records.

§ 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 heading).

The Department proposes to specify 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 proposal would provide the dual benefits of enabling agencies to move forward with investigations when they have unknowingly sought records from a Part 2 program and protecting patient privacy by ensuring agencies have clear responsibilities to continue protecting records even absent a court order. The proposal would limit 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.

§ 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 proposal would add 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 would ensure 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. Additionally, the reasonable diligence requirement would enhance patient privacy by ensuring that agencies consult available registries and visit websites or physical locations before placing agents in a position to access patients' records. As discussed above in reference to § 2.66, this proposal would also have the benefit of enhancing public safety and aid courts to streamline the application process for court orders for the use and disclosure of records.

§ 2.68 Report to the Secretary (proposed heading).

The Department's proposal to require annual reports by investigative agencies concerning applications for court orders made after receipt of Part 2 records would benefit programs, patients, and investigative agencies by making data available about the frequency of investigative requests made ''after the fact.'' This requirement would benefit 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 would benefit 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 proposed 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 Proposed Changes

The Department has estimated quantified costs and cost savings likely to result from its proposed regulatory modifications for two core expense categories (capital expenses and workforce training) and seven substantive regulatory requirements. The remaining proposed regulatory changes are unlikely to result in quantifiable costs or cost savings, as explained following the discussion of projected costs and savings.

Capital Expenses

Capital expenses related to compliance with the proposed 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 as compared to covered entities (774,331 × 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 × .02 = 1,170), and associated costs. Those costs are estimated on an ongoing annual basis because programs could experience a breach at any time that would require notification.

TABLE 5a—ESTIMATED CAPITAL EXPENSES—BREACH NOTIFICATION

Breach notification activity	Number of occurrences	Cost per occurrence	Total costs
Breach—Printing & Postage	[a] 1,170	[b] $719.96	$842,091
Breach—Posting Substitute Notice	[c] 55	480.00	26,362
Breach—Call Center	55	[d] 74.44	4,088
Total Costs			872,541

[a] Total number of breaches of PHI in 2015 multiplied by a factor of .02 to represent breaches of Part 2 records (58,482 × .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 × .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.

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 programs [211] at a rate of $0.10 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, NPP, 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 proposed changes would result in an estimated 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 $0.10 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 $372,873. The Department requests comment on its assumption and welcomes data that may help refine its estimates.

Additionally, covered entities and business associates that receive Part 2 records would also experience a reduced need to obtain written patient

[211] Substance Use Disorder Patient Records Supporting Statement A_06102020—OMB 0930–0092, *https://omb.report/omb/0930-0092*.

consent or a HIPAA authorization because redisclosure under the 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 $0.10,[212] this would result in annual savings of $93,218. 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.

TABLE 5b—ESTIMATED CAPITAL EXPENSE SAVINGS—PRINTING CONSENT FORMS

Activity	Number of occurrences	Cost per occurrence	Total cost savings
Reduction in Consent Forms for Part 2 Programs	3,728,734	$0.10	$372,873
Reduction in Consent Forms for CEs & BAs	932,184	0.10	93,218
Total Annual Savings			466,092

Training Costs

Although Part 2 does not expressly require training and the proposed rule would not require retraining, the Department anticipates that all Part 2 programs would choose to train their workforce members on the modified Part 2 requirements to ensure compliance. The Department estimates the potential costs that all Part 2 programs would incur to train staff on the changes to the confidentiality requirements if they are finalized as proposed. 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. As 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 would have no required Privacy Officer who is already assigned similar duties and would be more likely to incur costs for developing a new training regimen. The Department of Labor, Bureau of Labor Statistics (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 or NPP.[213] The Department estimates that a total of $12 million in one-time new training costs would be incurred in the first year of the final rule's implementation.

TABLE 6—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	12,049.50	$115.22	$1,388,343
Breach Notification—Manager	16,066	1	16,066.00	115.22	1,851,125
Obtaining Consent—Receptionist	32,132	0.5	16,066.00	31.64	508,328
Patient Notices & Right to Discuss—SUD Counselor	[a] 202,072	0.25	50,518.00	51.44	2,598,646
Requests for Restrictions—Receptionist, Medical Records, Billing Clerk	48,198	0.25	12,049.50	39.73	478,767
Accounting of Disclosures—Med. Records Specialist	16,066	0.5	8,033	46.46	373,213
Training Specialist's Time	16,066	5	80,330	65.02	5,223,057
Total Training Costs			167,354		12,421,479

[a] This figure is the number of substance abuse and behavioral disorder counselors as a proxy for the number of Part 2 program counselors.

iii. Notification of Breaches

The Department estimates annual labor costs of $1.5 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 Breach Notification Rule. This estimate is derived from calculating two percent of the total estimated breach notification activities for covered entities and business associates under the Breach Notification Rule.[214] Capital costs for providing breach notification are discussed separately in Table 5a above.

[212] The Department relies on its estimated capital expenses for printing HIPAA breach notification letters. *See* 2021 HIPAA ICR, *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-0945-001.*

[213] In 2021, that figure was 202,072 (310,880 × .65).

[214] *See* 2021 HIPAA ICR, *https://omb.report/icr/202011-0945-001.* Wage rates are updated to 2021 figures.

TABLE 7—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)	[a] 1,170	$51,230
164.404	Individual Notice—Written and E-mail Notice (preparing and documenting notification)	1,170	24,422
164.404	Individual Notice—Written and E-mail Notice (processing and sending)	1,170	758,452
164.404	Individual Notice—Substitute Notice (posting or publishing)	[b] 55	5,042
164.404	Individual Notice—Substitute Notice (staffing toll-free number)	55	7,844
164.404	Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information).	[c] 2,265	15,863
164.406	Media Notice	[d] 5.34	510
164.408	Notice to Secretary (notice for breaches affecting 500 or more individuals)	5.34	510
164.408	Notice to Secretary (notice for breaches affecting fewer than 500 individuals)	[e] 1,164	48,621
164.414	500 or More Affected Individuals (investigating and documenting breach)	5.34	30,764
164.414	Less than 500 Affected Individuals (investigating and documenting breach)—affecting 10–499.	50	45,701
164.414	Less than 500 Affected Individuals (investigating and documenting breach)—affecting <10.	[f] 1,115	513,752
Total			1,502,711

[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 × 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.

iv. Patient Notice and NPP

The Department estimates a first-year total of $2.4 million in costs to Part 2 programs for updating the Patient Notice and the NPP, as applicable, and providing patients a right to discuss the program's Patient Notice or NPP. Under the proposed modifications to § 2.22 and 45 CFR 164.520, as under the existing rules, a Part 2 program that is also a covered entity would only need 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 either its Patient Notice or its NPP. 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 8. The Department anticipates that the changed requirements for the NPP under this proposed rule and the HIPAA NPRM [215] would become effective at the same time so that covered entities would only incur costs for printing, mailing, and posting a revised NPP one time. There would be no new costs for providers associated with distribution of the revised notice other than posting it on the entity's website (if it has one), 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 Rule, in which the Department estimated approximately 613 million first time visits with health care providers annually.[216] Health plans that post their NPP online would incur minimal costs by posting the updated notice, and then, including the updated NPP in the next annual mailing to subscribers.[217] The Department estimates a potential increase in costs for health plans that do not post an NPP online or provide an annual mailing to subscribers. The increased costs would be associated with the requirement to mail an updated NPP to subscribers within 60 days of making a material change. The Department requests comments on the burdens on covered entity health plans of doing a separate mailing for the updated NPP if they are not subject to requirements in other law for an annual mailing, how many such entities there are, whether there should be an exception to allow entities to send it in the next three-year mailing, and any unintended adverse consequences for individuals of creating such an exception.

In addition to the costs of updating the Patient Notice and NPP, the Department estimates that programs would incur ongoing costs to implement the right to discuss a program's Patient Notice or NPP 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 $111,887 total per year. The number of discussions is based on the same percentage of new patients as the parallel proposal in the HIPAA NPRM, which reflects the anticipated number of patients who would ask to speak with the identified contact person about the NPP or 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.

v. 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 OCR'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 Privacy Rule. The Department included this estimate in its calculations (detailed in Table 8), although it is negligible, due to the CARES Act mandate to include the requirement in Part 2. The responses to OCR's 2018 Request for Information on Modifying HIPAA Rules to Improve Coordinated Care [218] indicated that

[215] 86 FR 6446.

[216] 78 FR 5675, *https://www.govinfo.gov/content/pkg/FR-2013-01-25/pdf/2013-01073.pdf).*

[217] 45 CFR 164.520(c)(1)(v)(A).

[218] 83 FR 64302 (December 14, 2018).

covered entities and their business associates receive very few requests for an accounting of disclosures annually (a high of .00006).[219] The Department is unable to estimate the additional burdens, if any, of offering these accountings in a machine readable or other electronic format (unless the individual requests otherwise). Further, the Department lacks specific information about the costs to revise electronic health record systems to generate a report of disclosures for TPO, other than they could be substantial.[220] The Department asks for public comments or information that will help to estimate these burdens.

Requests for Privacy Protection for Records

The Department estimates that Part 2 programs would incur a total of $1,590 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.[221] 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 details of the Department's estimate are noted in Table 8.

Updated Consent Form

The Department estimates that each 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 $1.5 million, to be incurred in the first year after publication of a final rule, as detailed in Table 8 below.

Updated Notice To Accompany Disclosures

The Department estimates that each 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 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 proposed regulation. 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 $0.6 million as detailed in Table 8 below.

New Reporting to the Secretary

The proposed reporting requirement in proposed § 2.68 would be directed to those agencies that investigate and prosecute programs and holders of Part 2 records. Part 2 programs are subject to investigations for Medicare and Medicaid fraud and diversion of opioids used in medication assisted treatment (MAT). Medicaid and Medicare fraud investigations may involve both the Department of Justice (DOJ) and the HHS Office of the Inspector General (OIG). The Department estimates that these agencies conduct approximately 225 investigations of Part 2 programs annually. For fiscal years 2019 and 2020 the HHS OIG reported the number of end-of-year open enforcement cases as 159 and 191, respectively, for an average of 175 per year, and annual criminal convictions and civil settlements or penalties totaling 19 and 16, respectively, for an average of 18 annual cases.[222] [223] Open Medicaid Fraud Cases of SUD Providers at end of FY 2020 included 140 criminal and 51 civil settlements or penalties for a total of 191.[224] At the end of FY 2019, the total was 159. Additionally, the Drug Enforcement Agency's (DEA) Drug Diversion Division reported actions against 50 registrants in 2020. The Department adds this number to the average of 175 health fraud cases, for an estimate of 225 investigations annually. The Department assumes, as an over-estimate, that all 225 cases targeted Part 2 programs and that all cases result in a required report under proposed § 2.68.

The burden on investigative agencies for annual reporting about unknowing receipt of Part 2 records prior to a court order would include 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 that of reporting large breaches of PHI under HIPAA which has been calculated at 1.5 hours per response at an hourly wage rate of $76.43 [225] for a total estimated cost of $114.65 per response. For an estimated 225 annual investigations this would result in a total cost of $25,794. This figure, albeit low, 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, and welcome comments and data to better inform all of the assumptions related to the estimated costs.

TABLE 8—ESTIMATED ANNUAL PART 2 COSTS IN FIRST YEAR OF IMPLEMENTATION

Activity	Total responses	Hours per response	Total burden hours	Hourly wage rate	Total cost
2.16 Breach Notification (from Table 7)	.....	.....	.....	.....	$1,502,714
2.22 Updating Patient Notice	16,066	1	16,066	$142.34	2,286,834
2.22 Right to Discuss	18,644	0.12	2,175	51.44	111,887
2.25 Accounting of Disclosures	100	0.05	5	46.46	232
2.26 Requests for privacy protection	800	0.05	40	39.20	1,590
2.31 Consent—Updating Form	16,066	0.67	10,711	142.34	1,524,556

[219] 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*).

[220] *Id.*

[221] 86 FR 6446, 6498. *See also* 84 FR 51604.

[222] HHS, Office of the Inspector General, Medicaid Fraud Control Units Fiscal Year 2020 Annual Report, Appendix C, Medicaid Fraud Control Unit Case Outcomes and Open Investigations by Provider Type and Case Type for Fiscal Year 2020, OEI–09–21–00120, March 2021, p. 25, *https://oig.hhs.gov/oei/reports/OEI-09-21-00120.pdf*, (FY 2020 Medicaid fraud convictions and civil penalties against outpatient SUD treatment providers included 9 criminal convictions and 7 civil settlements, for a total of 16).

[223] 2019 Report, *https://oig.hhs.gov/oei/reports/oei-09-20-00110.pdf*, (FY 2019 Medicaid fraud convictions and civil penalties against outpatient SUD treatment providers included 4 criminal convictions and 14 civil settlements for a total of 18).

[224] *Id.,* Exhibit C2, p. 28.

[225] This is a composite wage rate used in burden estimates for OCR's breach notification Information Collection Request.

TABLE 8—ESTIMATED ANNUAL PART 2 COSTS IN FIRST YEAR OF IMPLEMENTATION—Continued

Activity	Total responses	Hours per response	Total burden hours	Hourly wage rate	Total cost
2.32 Notice to Accompany Disclosures	16,066	0.33	5,355	115.22	617,042
2.68 Report to the Secretary	225	1.5	337.5	76.43	25,795
Workforce Training (from Table 6)					12,421,479
Capital Expenses (from Tables 5a)					872,541
Total Annual Costs (first year)					19,364,667

Proposed Changes Resulting in Negligible Fiscal Impact

§§ 2.1–2.4 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 proposed new or changed regulatory requirements. Thus, the Department's analysis does not estimate any program costs for the proposed changes to §§ 2.1 through 2.4 of 42 CFR part 2.

§ 2.11 Definitions.

Proposed 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 proposed definitions are generally intended to codify current usage and understanding of the defined terms.

§ 2.12 Applicability.

The proposal to change ''Armed Forces'' to ''Uniformed Services'' in paragraph (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 proceedings [226] 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 proposed 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.*

§ 2.13 Confidentiality restrictions and safeguards.

The primary proposed 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.

§ 2.14 Minor patients.

The proposed changes to this section would clarify that a program director may clinically evaluate whether a minor has decision making capacity, but not issue a legal judgment to that effect. The proposals would also add ''uses'' to ''disclosures'' as the types of activities regulated under this section. None of the proposed changes would be likely to result in quantifiable burdens to Part 2 programs.

§ 2.15 Patients who lack capacity and deceased patients.

The Department's proposed modification will 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.

§ 2.20 Relationship to state laws.

The Department proposes to add 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 proposed changes would result in a quantifiable increase or decrease in burden.

§ 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 that of the Privacy Rule. The edit does not require any changes to existing Part 2 requirements. The Department does not anticipate this proposed change would result in a quantifiable increase or decrease in burden.

§ 2.24 Requirements for intermediaries. (redesignated and proposed heading)

The Department estimates no change in burdens and benefits as a result of this regulatory clarification because no substantive change is intended.

§ 2.34 Uses and disclosures to prevent multiple enrollments.

The Department proposes to add 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 proposed changes would result in a quantifiable increase or decrease in burden.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

The Department proposes to replace 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 proposed changes would result in a quantifiable increase or decrease in burden.

§ 2.52 Scientific research (proposed heading)

[226] *See* 42 U.S.C. 290dd–2(c).

The Department considered whether the proposal to align the de-identification standard in § 2.52 (and throughout Part 2) with the 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 proposed 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 Privacy Rule standard. Additionally, the proposal would ensure 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.

§ 2.53 Management audits, financial audits, and program evaluation. (proposed heading)

The proposal to clarify 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 Privacy Rule. The Privacy Rule may allow these entities greater flexibility to use or redisclose the Part 2 records for permitted purposes as compared to the limitations contained in § 2.53 of Part 2. For Part 2 programs that are covered entities, this proposed 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 Privacy Rule.

§ 2.54 Disclosures for public health. (proposed heading)

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 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.

§§ 2.61–2.65 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.

§ 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 heading)

Proposed § 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 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 proposed 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. The proposed § 2.66 requirements to obtain a court order, 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. The Department requests comment on these assumptions and data on the burden for complying within 120 days of discovering that an investigative agency has unknowingly received Part 2 records.

§ 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 § 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 proposed § 2.3(b), which provides that steps such as checking an available prescription drug monitoring program (PDMP) or visiting the provider's website or physical location to determine if it is providing SUD-related services shall presumptively constitute reasonable diligence. 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 burden for checking a PDMP or a program's website or physical location 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 program. The proposed 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. The Department requests comment on the likely utilization of the proposed safe harbor involving undercover agents and informants.

f. Costs Borne by the Department

This rule would have a 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 proposed 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. HHS also would be required 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 proposals would require two full-time policy employees (or contractors) at the 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.[227] 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 initial posting of such breaches is automated, and HHS currently pays a contractor approximately $13,000 annually to maintain the database to receive reports of breaches from covered entities. The Department estimates approximately $13,000 to hire a second contractor to maintain the database to receive reports of breaches from Part 2 programs. Additionally, HHS drafts and posts summaries of each large breach on the website at a labor cost of approximately $22,600 per year. To implement these policies, the Department estimates that initial Federal costs will be approximately $1,695,716 million. The Department estimates that based on the GS within grade step increases for each of the proposed GS–13 and GS–14 employees the Federal costs will be approximately $8,972,716 million over 5 years.

Comparison of Benefits and Costs

TABLE 9a—PART 2 COSTS AND SAVINGS OVER 5-YEAR TIME HORIZON

Cost item	5-Year costs	5-Year savings
2.16 Breach Notice	$7,513,554	.....
2.22 Patient Notice & Right to Discuss	2,846,269	.....
2.25 Accounting of Disclosures	1,162	.....
2.26 Requests for Restrictions	7,948	.....
2.31 Updating Consent Form	1,524,556	.....
2.32 Updating Disclosure Notice	617,042	.....
2.68 Reporting to the Secretary	129,364	.....
Training	12,421,479	.....
Capital Expenses	4,362,706	($2,330,459)
Obtaining Consent	.....	(61,446,429)
Total	29,424,093	(63,776,888)
Net Savings/Costs	.....	(34,353,198)

TABLE 9b—PRIVACY RULE COSTS AND SAVINGS OVER 5-YEAR TIME HORIZON

Cost item	5-Year costs	5-Year set–off (savings)
45 CFR 164.520 NPP	$36,739,425	.....
45 CFR 154.520 Capital Costs	8,195,800	.....
Total	44,935,225	.....
Net Savings/Costs	.....	($44,935,225)

TABLE 9c—COMBINED PART 2 AND PRIVACY RULE COSTS AND SAVINGS OVER 5-YEAR TIME HORIZON

Cost item	5-Year costs	5-Year set-off (savings)
2.16 Breach Notice	$7,513,554	.....
2.22 Patient Notice & Right to Discuss	2,846,269	.....
2.25 Accounting of Disclosures	1,162	.....
2.26 Requests for Restrictions	7,948	.....
2.31 Updating Consent Form	1,524,556	.....
2.32 Updating Disclosure Notice	617,042	.....
2.68 Reporting to the Secretary	128,976	.....
Training	12,421,479	.....
Capital Expenses (Part 2)	4,362,706	($2,330,459)

[227] To determine the salary rate of the employees at the GS–13 and GS–14 pay scale, the Department used the U.S. Office of Personnel Management's (OPM's) General Schedule (GS) classification and pay system and used the Department's General Schedule (Base) annual rates. The Department used the available 2021 data for the estimated costs. In 2021, the salary table for schedule GS–13, step 1 annual rate is $158,936, including $79,468 plus 100% for benefits and the GS–14, step 1 annual rate is $187,814, including $93,907 plus 100% for benefits. The Department estimated the costs over 5 years based on within-grade step increases based on an acceptable level of performance and longevity (waiting periods of 1 year at steps 1–3 and 2 years at steps 4–6).

TABLE 9c—COMBINED PART 2 AND PRIVACY RULE COSTS AND SAVINGS OVER 5-YEAR TIME HORIZON—Continued

Cost item	5-Year costs	5-Year set-off (savings)
Obtaining Consent		(61,446,429)
45 CFR 164.520 NPP	36,739,425	
45 CFR 164.520 Capital Expenses	8,195,800	
Total	74,359,318	(63,776,888)
Net Savings/Costs		10,582,027

TABLE 10—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 NPP		Improved understanding of individuals' 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 protection 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 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.

4. Consideration of Regulatory Alternatives

The Department carefully considered several alternatives to the proposals in this NPRM. The Department welcomes public comment on any benefits or drawbacks of the following alternatives it considered while developing the NPRM.

Definitions for ''breach,'' ''health care operations,'' ''lawful holder,'' and ''third-party payer.''

Breach. The Department considered adopting only the first sentence of the HIPAA definition of breach in the introductory text of the paragraph and not the remainder of the definition. The Department considered that the HIPAA definition, which includes exclusions from the term breach (*i.e.,* unintentional access, inadvertent disclosure, disclosure based on good faith belief that an unauthorized recipient would not reasonably been able to retain the information) did not offer a parallel level of protection to Part 2 records as is intended by its overall structure of requiring consent for most disclosures. However, due to the amount of overlap between the types of entities that must comply with both Part 2 and the HIPAA Rules, the Department decided to adopt the HIPAA breach definition in its entirety. Congress was aware of the Breach Notification Rule when it passed the CARES Act, so the Department

assumes that Congress intended to apply the full scope of the definition to Part 2 records. The Department welcomes comments on any unintended negative consequences of this approach and how any alternative approaches could be implemented consistent with Congressional intent.

Health care operations. The Department considered including the ''Sense of Congress'' in section 3221(k)(4) of the CARES Act, which states that the definition of health care operations shall have the same meaning as provided in the HIPAA Rules except that clause (v) of paragraph (6) shall not apply. This would have had the effect of excluding from the HIPAA disclosure and redisclosure permissions the use of records for fundraising. In contrast, the Department also considered not including the Sense of Congress in any provision of the proposed rule. This would have narrowly hewed to the statutory amendment mandated by section 3221 of the CARES Act without acknowledging Congressional intent. Instead, the Department proposed to add an opt-in approach for fundraising activities in the requirements for a written consent proposed at § 2.31(a)(5). The Department similarly is proposing in § 2.22 and 45 CFR 164.520 to require that programs and covered entities provide notice to a patient that the use and disclosure of records for such activities may be made only with the patient's written consent. The Department welcomes comments on any unintended adverse consequences of this approach and how any alternative approaches could be implemented consistent with statutory authority and Congressional intent.

Lawful holder. Although not required by the CARES Act, the Department considered proposing a new regulatory definition for the term ''lawful holder,'' which is not currently defined in Part 2. The definition would be drawn from the Department's descriptions of lawful holders in previous Part 2 proposed and final rule preambles.[228] In particular, the Department considered whether the definition was needed to distinguish the category of records recipients that includes covered entities, business associates, qualified service organizations, and other components of the health care system from other types of recipients of records based on a written patient consent for purposes of applying different requirements to the different categories.

SAMHSA has described a lawful holder as ''an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a notice to accompany 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.'' [229] Further, § 2.33(a) provides that a valid consent may name *any* person or category of persons: ''If a patient consents to a disclosure of their records under § 2.31, a [P]art 2 program may 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.'' Taken together, the description of lawful holder and provision on consent mean that any person who receives records pursuant to a valid consent could be considered a lawful holder, and thus subject to the Part 2 requirements that apply to lawful holders.

The Department is concerned that some of the restrictions and obligations placed on lawful holders are not appropriate to apply across all types of persons who receive Part 2 records pursuant to a consent. For example, a patient's family member who receives a record based on consent could not be reasonably expected to develop policies and procedures for securing records. To address this concern, the Department considered proposing a definition that would exclude certain types of persons, such as those who are acting in their capacity as private citizens (rather than in a professional or official capacity as part of the health care system or government authority, for example). The Department also considered a definition that would expressly include only covered entities, Part 2 programs, any person conducting diagnosis, treatment, or referral for treatment, billing or payment, and any other purpose related to a patient's enrollment or participation in a Part 2 program. However, the Department is concerned that inserting a new definition in regulatory text may inadvertently exclude persons who rightfully should be subject to Part 2 requirements and restrictions that apply to both Part 2 programs and lawful holders.

The Department has considered that a small minority of recipients of Part 2 records based on a patient's consent may not be properly subject to regulatory requirements that apply only to Part 2 programs and lawful holders. For example, it is unclear how the Department would enforce organizational requirements, such as policies and procedures, against some persons who receive records based on written consent, such as natural persons who are family members of a patient and are not acting in any professional or official capacity.

Therefore, rather than propose a regulatory definition or create an enforcement exception, the Department instead asks for comment on what would be reasonable to expect of a person who is a lawful holder, but not a covered entity, business associate, or qualified service organization with respect to protecting records against unauthorized use and disclosure or security threats. The Department requests comment on whether it would be appropriate to include a definition of lawful holder—and, if so, what persons should be considered lawful holders.

Third-party payer. The Department considered removing the term ''third-party payer'' from the regulations because the definition is limited to entities with a contractual obligation to pay for Part 2 services, many of which are covered entity health plans to whom Part 2 redisclosure restrictions will no longer apply. Upon further consideration, the Department determined that some Part 2 programs may be paid based on a contractual obligation between the payer and the patient, but by entities other than a health plan. Retaining a narrower definition of third-party payer rather than removing the definition entirely would ensure that the restrictions on redisclosure are maintained for any third-party payers that are not covered entities. The Department welcomes data on how many and what types of third-party payers are not covered entities.

Exception for reporting suspected abuse and neglect.

The Department considered 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 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

[228] *See* 81 FR 6988; *See also* 82 FR 6052.

[229] 82 FR 6052, 6068.

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.

Security of records and notification of breaches.

The Department considered retaining the current language in § 2.16 (a)(1)(v) with respect to ''non-identifiable'' information and adding a reference to the Privacy Rule standard with the phrase ''as consistent with 45 CFR 164.514.'' Upon consideration, the Department decided instead to insert text from the Privacy Rule de-identification standard and a reference to 45 CFR 164.514 to more closely align the two sets of regulations.

The Department also considered further harmonizing Part 2 and the HIPAA Rules by applying the Security Rule, or components of it, to Part 2 programs and other lawful holders with respect to electronic Part 2 records. The Security Rule contains standards and implementation specifications for securing electronic PHI that are consistent with industry best practices, and the implementation of robust security safeguards can prevent many breaches of patients' Part 2 records. However, the CARES Act did not make the Security Rule applicable to Part 2 programs. Therefore, the Department believes it does not have statutory authority to the Security Rule to encompass Part 2 programs that are not covered entities or business associates. The Department requests comment on this interpretation and on whether the Part 2 security provisions should be modified to incorporate additional or different safeguards consistent with the Security Rule.

Patient Notice and NPP.

The Department considered proposing more limited modifications to the Patient Notice in § 2.22 to narrowly address only those changes specifically identified in section (i)(2) of the CARES Act, without incorporating into the Patient Notice other aspects of the NPP. However, the Department determined that greater alignment between the requirements of the Patient Notice and NPP would create more consistency in notices among Part 2 programs and other types of health care providers, and thus more consistency in patients' understanding and expectations regarding their rights and regulated entities' duties with respect to their Part 2 records.

Adding a requirement for notification of TPO consent.

The Department considered adding a requirement to § 2.32 to require Part 2 programs to notify the recipient that a record is being disclosed to them pursuant to a global consent for TPO or whether it is a more limited consent. The Department considered how this might help covered entities to avail themselves of the new redisclosure permissions enacted into the CARES Act by section 3221(b) so that they would be aware when they could redisclose a record according to the HIPAA Rules. However, the Department determined that this would be unduly burdensome on Part 2 programs. The Department requests comment on this alternative and the extent to which covered entities that receive Part 2 records are aware of the purpose of the disclosure and how that information is conveyed between programs and covered entity recipients of Part 2 records.

Adding a new definition for ''confidential communications.''

The Department considered adding a new definition for ''confidential communications'' as an alternative modification to § 2.63 (confidential communications). Specifically, the Department considered whether to propose incorporating in regulatory text a preamble description of ''confidential communications'' from prior Part 2 rulemaking, which describes the term as ''the essence of those matters to be afforded protection'' and ''highly sensitive communication.'' [230] The Department did not propose this approach as it is only used in one specific context and a new definition would likely create unnecessary complexity without improving understanding of the regulatory requirements.

Creating limitations on liability for investigative agencies' unknowing receipt of Part 2 records.

The Department considered creating an enforceable requirement for Part 2 programs to notify investigative agencies of the applicability of Part 2 when presented with an investigative demand for records, but deemed this an unnecessary burden on programs. Instead, the Department created prerequisites for investigative agencies to meet before they could benefit from liability protection, and thus avoided any increased burden on programs.

[230] 52 FR 21801 (June 9, 1987).

5. Request for Comments on Costs and Benefits

The Department requests public comment on all the estimates, assumptions, and analyses within the cost-benefits analysis, including the costs to regulated entities and patients. The Department also requests comments on any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA. The Department also requests comments on whether there may be other indirect costs and benefits resulting from the proposed changes in the proposed rule and welcomes additional information that may help quantify those costs and benefits.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this proposed 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. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organization, the Department generally treats all health care providers as small entities for purposes of performing a regulatory flexibility analysis. The SBA size standard for health care providers ranges between a maximum of $8 million and $41.5 million in annual receipts, depending upon the type of entity.

The projected costs and savings are discussed in detail in the regulatory impact analysis (section 3a). This proposed rule would create average net costs for regulated entities (Part 2 programs and covered entities), many of which are small entities, and the proposed changes are needed to implement required statutory changes. As its measure of significant economic impact on a substantial number of small entities, HHS uses a threshold for the size of the impact of 3 to 5 percent. The

total costs from this rule are estimated to be $10,582,027, spread across 774,331 small entities. The average cost per small entity over 5 years is equal to $13.67, and we do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary certifies that this proposed rule would not result in a significant negative impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act

Section 202(a) of The Unfunded Mandates Reform Act of 1995 (UMRA) 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. In 2021, that threshold is approximately $158 million. The Department does not anticipate that this proposed rule would result in the expenditure by state, local, and tribal governments, taken together, or by the private sector, of $158 million or more in any one year. The proposals, however, present novel legal and policy issues, for which the Department is required to provide an explanation of the need for this proposed rule and an assessment of any potential costs and benefits associated with this rulemaking in accordance with Executive Orders 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 Privacy, Security, Breach Notification, and Enforcement Rules were assessed as required by Executive Order 13132 and published as part of the preambles to the final rules on December 28, 2000,[231] February 20, 2003,[232] and January 25, 2013.[233] Regarding preemption, the preamble to the final Privacy Rule explains that the HIPAA statute dictates the relationship between state law and Privacy Rule requirements, and the 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 the preamble to proposed rules on February 9, 2016.[234]

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 or NPPs for individuals with first-time health encounters. The regulatory impact analysis above addresses these costs in detail.

In considering the principles in and requirements of Executive Order 13132, the Department has determined that these proposed modifications to the Privacy 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 1999 [235] requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The 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 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 Office of Management and Budget (OMB) for review and approval any reporting or record-keeping 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 explicitly seeks, and will consider, public comment on its assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, email your comment or request, including your address and phone number to *Sherrette.Funn@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

As discussed below, the Department estimates a total program burden associated with all proposed Part 2 changes of 565,029 hours and $43,911,857, 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 35 hours and $2,733 per Part 2 program and 0.30 hours and $24 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 22 hours and $1,704 per Part 2 program and 0.19 hours and $15 per patient admission. In addition to program burdens, the Department's proposals would increase burdens on investigative agencies for

[231] 65 FR 82462, 82797.

[232] 68 FR 8334, 8373.

[233] 78 FR 5566, 5686.

[234] 81 FR 6987, 7012.

[235] Public Law 105–277, 112 Stat. 2681 (October 21, 1998).

reporting annually to the Secretary in the collective amount of 338 hours of labor and $25,795 in costs. This would result in a total burden for Part 2 of 565,367 hours in the first year after the rule becomes effective and 350,172 annual burden hours thereafter.

Further, due to the proposed changes to 45 CFR 164.520, covered entities may need to update their NPP in order to comply with the documentation requirements of 45 CFR 164.530. Section 164.530 contains the administrative requirements for covered entities, including documenting training of personnel, updating policies and procedures, and updating the NPP in accordance with changes in the law.[236] Due to these proposals, the burden for respondent covered entities to comply with the requirements of the suite of HIPAA Rules (Privacy, Breach Notification, Security, and Enforcement) would increase by 258,110 burden hours.

In this NPRM, 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. The Department is also revising the NPP information collection requirements in OCR's HIPAA ICR previously approved under OMB control #0945–0003. The estimated burdens of these proposed changes are shown in the tables that follow.

1. Explanation of Estimated Annualized Burden Hours for 42 CFR Part 2

The Department presents, in separate tables below, revised estimates for existing burdens (Table 11), previously unquantified ongoing burdens (Table 12), new ongoing burdens of the proposals (Table 13), and new one-time burdens of the proposals (Table 13).

TABLE 11—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	[a] 1,864,367	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	[c] 16,066	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.	[d] 125,845	1	125,845	0.083	10,487
2.52	Disclosures for Research—Paper	[e] 13,983	1	13,983	0.250	3,496
2.53	Disclosures for Audit & Eval.—Elec.	[f] 125,845	1	125,845	0.083	10,487
2.53	Disclosures for Audit & Eval.—Paper	[g] 13,983	1	13,983	0.250	3,496
Total Ongoing Burdens, Currently Approved [237]				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.

As shown in Table 11, 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 National Survey of Substance Abuse Treatment Services (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 Treatment Episode Data Set (TEDS) as the number of annual patient 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.[238] 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 proposed changes to the consent requirements, the Department assumes that programs would experience a decreased burden from an average of 3 consents per admission to 1 consent. The Table above 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 12, below.

The Department previously estimated that for § 2.31 (consent), § 2.52 (research), and § 2.53 (audit and

[236] *See* 45 CFR 164.530(i)(3).

[237] This refers to approved information collections; however, the burden hours shown are adjusted for the NPRM.

[238] 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.

evaluation) combined, programs would need to disclose an average of 15 percent of all patients' records (1,864,367 records × .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 × 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 ÷ 16,066 programs) and 176.03 PDMP updates per respondent (35.21 patients/program × 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 × 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 12—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	[a] 1,864,367	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 12, for § 2.31 the Department is recognizing for the first time the burden on 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 × 3).

As shown in Table 11, 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 × .5), and this also represents a previously unquantified burden. Together, this would result in an increase of 2.5 consents annually per patient. However, this would be offset by the changes proposed in this NPRM which would 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.

TABLE 13—ANNUALIZED ESTIMATES FOR PROPOSED NEW BURDENS

Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
Individual Notice—Written and E-mail Notice (drafting)	[a] 1,170	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	[b] 2,270,271	0.008	18,162
Individual Notice—Substitute Notice (posting or publishing)	55	1	55	1	55
Individual Notice—Substitute Notice (staffing toll-free number)	[c] 55	1	55	[d] 3.42	188
Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information)	[e] 2,265	1	2,265	[f] .125	283
Media Notice	[g] 5	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)	[h] 1,164	1	1,164	1	1,164
500 or More Affected Individuals (investigating and documenting breach)	[i] 5	1	5.34	50	267
Less than 500 Affected Individuals (investigating and documenting breach)—affecting 10–499	[j] 50	1	49.58	8	397

TABLE 13—ANNUALIZED ESTIMATES FOR PROPOSED NEW BURDENS—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
Less than 500 Affected Individuals (investigating and documenting breach)—affecting <10	[k] 1,115	1	1,114.72	4	4,459
Right to Discuss Patient Notice or NPP	[l] 18,644	1	18,644	0.12	2,175
Accounting for Disclosures of Part 2 Records	[m] 100	1	800	0.05	5
Rights to Request Restrictions	[n] 800	1	800	0.05	40
Report to the Secretary	[o] 225	1	225	1.5	338
			2,297,574		28,378

[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 02.
[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 .02 to represent requests from Part 2 patients.
[o] 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 13 above, the Department shows an annualized new hourly burden of approximately 28,378 hours due to proposed regulatory requirements for breach notification, accounting of disclosures of records, responding to patient's requests for restrictions on disclosures, discussing the Patient Notice, 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 (16,066/771,334 = .02). The Department recognizes that this is an overestimate because an unknown proportion of Part 2 programs are also covered entities. The total in Table 13 also includes the Department's estimates for a recurring annual burden on investigative agencies of 338 hours, relying on previous estimates for the burden of reporting breaches of PHI to the Secretary at 1.5 hours per report.

TABLE 14—ESTIMATES FOR PROPOSED 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)	[a] 16,066	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	202,072	0.25	50,518
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 to Accompany Disclosure (manager)	16,066	1	16,066	0.333	5,355
Training Specialist's Time	16,066	1	16,066	5	80,330

TABLE 14—ESTIMATES FOR PROPOSED NONRECURRING NEW BURDENS—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
Total			394,862		215,195

[a] Estimated total number of Part 2 programs.

As shown in Table 14, the Department estimates one-time burden increases as a result of proposed changes to § 2.16, § 2.22, § 2.31, and § 2.32 and due to proposed new provisions § 2.25 and § 2.26. The proposed nonrecurring burdens are for training staff on the proposed provisions and for updating forms and notices. The Department estimates that each 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 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 hours 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 50,518 total burden hours).

For § 2.25, the Department estimates that each program would need to train a medical records specialist on the requirements of proposed 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 program would need to train three staff (a front desk receptionist, a medical records technician, and a billing clerk (16,066 Part 2 programs × 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 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 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 proposed regulations, 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 programs that are using the short form notice could continue using the same notice and avoid any burden increase.

2. Explanation of Estimated Capital Expenses for 42 CFR Part 2

TABLE 15—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	$719.95	$842,091.28
164.404	Individual Notice—Substitute Notice Media Posting	55	480.00	26,361.60
164.404	Individual Notice—Substitute Notice—Toll-Free Number	55	74.44	4,088.24
Total Breach				872,541.12
Part 2 section	**Activity**	**Number of notices**	**Average cost per notice**	**Total notice cost**
2.22	Printing Patient Notice	932,184	0.10	$93,218.35
2.31	Printing Consent Form	932,184	0.10	93,218.35
2.32	Printing Notice to Accompany Disclosure	186,437	0.10	18,643.67
Total Part 2 Forms				205,080.37
Total Capital Costs				1,077,621.49

* Not all decimal places are shown.

As shown above in Table 15, 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.[239]

3. Explanation of Estimated Annualized Burden Hours for 45 CFR 164.520

[239] *See* Molfenter T, Roget N, Chaple M, Behlman S, Cody O, Hartzler B, Johnson E, Nichols M, Stilen P, Becker S, Use of Telehealth in Substance Use Disorder Services During and After COVID–19: Online Survey Study, JMIR Ment Health 021;8(2):e25835, *https://mental.jmir.org/2021/2/e25835.*

TABLE 16—NEW NONRECURRING BURDENS OF COMPLIANCE FOR 45 CFR 164.520

[As required by 45 CFR 164.530]

Privacy rule section	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
164.530	Administrative Requirements—Policies & Procedures—Revising the Notice of Privacy Practices, 164.520.	[a] 774,331	1	774,331	[b] .333	258,110
Total	.....	.....	.....	774,331	.....	258,110

[a] Total number of covered entities.
[b] Not all decimal places are shown.

As shown in Table 16, above, the Department proposes increasing the estimated number of covered entities from 700,000 to 774,331 due to updating the estimated the total number of covered entities, consistent with its estimates associated with the HIPAA NPRM published on January 21, 2021.[240] The Department also proposes adding one new burden element for covered entities to update the NPP as required by 45 CFR 164.530 to include the proposed revisions to 45 CFR 164.520. This burden estimate is primarily applicable to covered entities that receive or maintain Part 2 records because the burdens for covered entities that create Part 2 records (*i.e.,* that are Part 2 programs) are addressed in the Part 2 ICR, discussed above. However, the Department recognizes this likely overestimates the overall compliance burden on covered entities because some covered entities may not receive or maintain Part 2 records and may find the Part 2 NPP language is not applicable. The Department estimates that each covered entity that is not a Part 2 program would incur the burden of 20 minutes of a lawyer's time to evaluate how the modifications may apply to them and to update the NPP accordingly. The Department estimates 258,110 total one-time burden hours in the first year attributable to the proposed changes to 45 CFR 164.520 in this NPRM and no additional burden thereafter.

List of Subjects

42 CFR Part 2

Administrative practice and procedure, Alcoholism, Administrative practice and procedure, Alcohol use disorder, 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, HIPAA, HITECH Act, Hospitals, Investigations, Medicaid, Medical research, Medicare, Part 2, Part 2 programs, Patient rights, Penalties, Privacy, Reporting and record keeping requirements, Security measures, Substance use disorder, SUD.

45 CFR Part 164

Administrative practice and procedure, Breach, Confidentiality, Courts, Drug abuse, Electronic information system, Health, Health care, Health care operations, Health information exchange, Health plan, Health records, HIPAA, HITECH Act, Hospitals, Individual rights, Investigations, Medicaid, Medical research, Medicare, Part 2, Patient rights, Penalties, Privacy, Reporting and record keeping requirements, Security measures, Substance use disorder, SUD.

Proposed Rule

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 42 CFR part 2 and 45 CFR part 164 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: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303(a), (b) of Pub. L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2), as amended by sec. 3221 of Pub. L. 114–136.

■ 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. Amend § 2.2 by revising paragraphs (a) introductory text, (a)(2), (a)(3), (a)(4), (b)(1), (b)(2), and (b)(3) 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:

* * * * *

(2) Subpart C of this part: Uses and Disclosures with Patient Consent, including uses and disclosures that require patient consent and the consent form requirements;

(3) Subpart D of this part: 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 of this part: Court Orders Authorizing Use and Disclosure, including uses and disclosures of records which may be made with an

[240] *See* Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446.

authorizing court order and the procedures and criteria for the entry and scope of those orders.

(b) * * * (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 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) of this part.

(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) 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.

(b) 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 part 2 records (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, program, or other person holding part 2 records. The following actions are sufficient to constitute reasonable diligence when made 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 where it is reasonable to believe that the practice or provider provides substance use disorder diagnostic, treatment, or referral for treatment services:

(i) consulting a prescription drug monitoring program database in the state where the investigative agency's investigation is occurring, where such database is available and accessible by the investigative agency under state law, or

(ii) checking a practice's or provider's publicly available website or physical location to determine whether in fact such services are provided.

(2) The investigative agency followed all of the applicable provisions in this part for any use or disclosure of the received part 2 records that occurred, or will occur, after the investigative agency knew, or by exercising reasonable diligence would have known, that it received part 2 records.

(c) The provisions of 45 CFR part 160, subparts C, D, and E, shall apply to part 2 programs for violations of 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 protected health information.

■ 5. Revise § 2.4 to read as follows:

§ 2.4 Complaints of Violations.

(a) A part 2 program must provide a process to receive complaints concerning the program's compliance with the requirements of this part.

(b) 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).

(c) 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''; ''HIPAA regulations'';

■ b. In the definition of ''Informant'' revising the introductory text;

■ c. Adding in alphabetical order definitions of ''Intermediary''; and ''Investigative agency'' ';

■ d. Revising the definition of ''Part 2 program director'';

■ e. Adding a sentence at the end of the definition of ''Patient'';

■ f. Adding in alphabetical order the definition of ''Payment'';

■ g. Revising the definition of ''Person'';

■ h. In the definition of ''Program'' revising paragraph (1);

■ i. Adding in alphabetical order the definition of ''Public health authority'';

■ j. In the definition of ''Qualified service organization'' revising the introductory text, paragraph (2) introductory text, and adding paragraph (3);

■ k. Revising the definition of ''Records'', ''Third-party payer'', ''Treating provider relationship'', and ''Treatment'';

■ l. 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 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 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.

* * * * *

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 provisions where the HIPAA regulations apply in this part, *Patient* means an individual as that term is defined in 45 CFR 160.103.

* * * * *

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.

Program * * *

(1) A person (other than a general medical facility) who 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) A *qualified service organization* includes a person who meets the definition of *Business associate* in 45 CFR 160.103, paragraphs (1), (2), and (3), 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 non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider.

* * * * *

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 paragraphs (c)(2), (c)(3) introductory text, (c)(4), (c)(5) introductory text and (c)(6);

■ c. Revising paragraphs (d)(1) and (2); and

■ d. 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.* 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.

* * * * *

(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

(ii) Any interchange of that information between the Uniformed Services and those components of the Department of Veterans Affairs furnishing health care to veterans.

(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 in 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 form part of the record for 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. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use and disclosure.

(2) *Restrictions on use 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 or other lawful holder of patient identifying information and who are notified of the prohibition on redisclosure in accordance with § 2.32.

(ii) Notwithstanding paragraph (d)(2)(i)(C) of this section, a non-part 2 treating provider may record information about a substance use disorder and its treatment that identifies a patient. This is permitted and does not constitute a record that has been redisclosed under part 2, provided that any substance use disorder records received from a part 2 program or other lawful holder are segregated or segmented. The act of recording information about a substance use disorder and its treatment does not by itself render a medical record which is created by a non-part 2 treating provider subject to the restrictions of this part 2.

* * * * *

(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

* * * * *

■ 7. Amend § 2.13 by revising paragraphs (a), (b) and (c)(1) and removing paragraph (d) to 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.

* * * * *

■ 8. 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. These regulations 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.

■ 9. Amend § 2.15 by revising the section heading, 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 guardian or other person authorized under state law to act on the patient's behalf.

(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 an executor, administrator, or other personal representative appointed under applicable state law. If there is no such applicable state law appointment, the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

■ 10. Amend § 2.16 by:

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1)(v), and (a)(2)(iv); and

■ b. Adding paragraph (b).

The revisions and addition 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. These formal policies and procedures must address all of the following:

(1) * * *

(v) Rendering 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 particular patient as having or having had a substance use disorder.

(2) * * *

(iv) Rendering the 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.

(b) The provisions of 45 CFR part 160 and subpart D of 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.

■ 11. Amend § 2.17 by revising paragraph (b) to read as follows.

§ 2.17 Undercover agents and informants.

* * * * *

(b) *Restriction on use 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.

■ 12. Amend § 2.19 by:
■ a. Adding paragraph (a)(3);
■ b. 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) * * *

(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.

(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.

■ 13. 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.

■ 14. 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.* These regulations restrict the use and disclosure of information about patients, while administrative action taken under the research privilege statutes and implementing regulations 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.

■ 15. 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), 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.

(1) 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 [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 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 of this part.

(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 42 CFR part 2; and

(*3*) A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed.

(iii) *Separate statements for certain uses or disclosures.* If the 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 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 program, covered entity, or business associate, without the patient's written consent, to the extent the HIPAA Privacy Rule permits such disclosure.

(B) Records that a program, covered entity, or business associate intends to use or disclose to fundraise for the benefit of the program, covered entity, or business associate, may be used or disclosed only with your valid written consent that complies with the requirements of 42 CFR part 2.

(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 42 CFR 2.26.

(B) Right to 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 disclosures of protected health information.

(C) Right to an accounting of disclosures of electronic part 2 records for the past 3 years, as provided in 42 CFR 2.25, and a right to an accounting of disclosures that meets the requirements of 45 CFR 164.528(a)(2) and (b)–(d) for all other disclosures made with consent.

(D) Right to obtain a paper or electronic copy of the notice from the program upon request.

(E) Right to discuss the notice with a designated contact person identified by the part 2 program pursuant to paragraph (b)(1)(vii).

(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 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 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:

(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 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 paragraph (c) of this section 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.

■ 16. 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).

■ 17. 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 provision, patient requests:

(1) Must be made in writing; and

(2) Are limited to disclosures made within the past three years.

(b) Under this provision, 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.

■ 18. 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 six 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)–(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 three years prior to the date on which the accounting is requested.

■ 19. 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 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 regulation for purposes other than treatment, payment, and health care operations, as defined in this regulation.

(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 program in full.

(b) A 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 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.

■ 20. Revise the heading of subpart C to read as follows:

Subpart C—Uses and Disclosures With Patient Consent

* * * * *

■ 21. Amend § 2.31 by:

■ a. Revising paragraph (a) introductory text, and paragraphs (a)(2) through (a)(8);

■ b. Adding paragraph (a)(10); and

■ c. Revising paragraph (b)(4).

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 program, 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 as defined in this part, 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 Privacy Rule, 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) Fundraising. If applicable, a statement that a patient consents to the use or disclosure of the patient's records for the purpose of fundraising for the benefit of the program.

(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 lacks 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) * * *

(4) Is known, or through reasonable diligence could be known, by the person holding the records to be materially false.

■ 22. Amend § 2.32 by revising the section heading and paragraph (a) to read as follows:

§ 2.32 Notice to accompany disclosure.

(a) *Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by one of the following written statements (*i.e.,* either (a)(1) or (a)(2) of this section):

(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 and compelled by subpoena or other legal requirement. 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 is 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 as defined in this part, 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.

(iv) 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) 42 CFR part 2 prohibits unauthorized use or disclosure of these records.

* * * * *

■ 23. 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, a part 2 program may 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.

(b) If 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:

(1) When disclosed for treatment, payment, and health care operations activities as defined in this part, to a program, 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.

(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 use or 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, 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.

(c) Lawful holders, other than covered entities and business associates, who wish to redisclose patient identifying information pursuant to paragraph (b)(2) 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 part 2 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 or subcontractor or voluntary legal representative to perform its duties under the contract or comparable legal instrument. Contracts may not permit a contractor or 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.

■ 24. 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.

* * * * *

■ 25. 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) 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.

■ 26. Revise the heading of subpart D to read as follows:

Subpart D—Uses and Disclosures Without Patient Consent

* * * * *

■ 27. 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;

* * * * *

■ 28. Amend § 2.52 by:
■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1) introductory text and (a)(2);
■ b. Revising paragraphs (b) introductory text, (b)(2) and (3);
■ c. Revising paragraph (c)(1) introductory text and adding paragraph (c)(1)(iii); and
■ d. Removing the second paragraph (c)(2).

The revisions and addition read as follows:

§ 2.52 Scientific research.

(a) 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 part 2 data, makes a determination that the recipient of the patient identifying information is:

* * * * *

(2) The part 2 program or other lawful holder of part 2 data is a HIPAA covered entity or business associate, and the use or disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i).

* * * * *

(b) 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 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.

* * * * *

(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 paragraph (c) of this section.

* * * * *

■ 29. Amend § 2.53 by:
■ a. Revising the section heading;
■ b. Revising paragraph (a) introductory text and paragraph (a)(1)(ii);
■ c. Revising paragraphs (b) introductory text, (b)(1)(iii) and (b)(2)(ii);
■ d. Revising paragraphs (c)(1) introductory text and (c)(1)(i);
■ e. Revising paragraphs (e)(1) introductory text, (e)(1)(iii), (e)(5), and (e)(6);
■ f. Revising paragraph (f); and
■ g. 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 performing a QIO review, or the contractors, subcontractors, or legal representatives of such person or quality improvement organization.

* * * * *

(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 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 paragraph (e) of this section.

(f) *Limitations on use and disclosure.* Except 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.

* * * * *

(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 Privacy Rule if the recipient is a part 2 program, covered entity, or business associate.

■ 30. 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 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 has having or having had a substance use disorder.

■ 31. Revise the heading of subpart E to read as follows:

Subpart E—Court Orders Authorizing Use and Disclosure

* * * * *

■ 32. 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 in order 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.

■ 33. 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)–(iii) of this part, 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.

■ 34. Amend § 2.63 by revising paragraph (a)(3) to read as follows:

(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.

* * * * *

■ 35. Amend § 2.64 by by revising the section heading, paragraph (a), paragraph (b) introductory text, (d) 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.

■ 36. Amend § 2.65 by revising the section heading, 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.

■ 37. Amend § 2.66 by

■ a. Revising the section heading and paragraph (a)(1);

■ b. Adding new 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 part 2 records 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) 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 part 2 records; 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 part 2 records; 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 part 2 records; or.

(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).

(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.

■ 38. 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.

(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.

■ 39. 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 part 2 records 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].

* * * * *

Title 45—PUBLIC WELFARE

PART 164—SECURITY AND PRIVACY

■ 40. The authority citation for part 164 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279 (42 U.S.C. 17921, 17931–17954); and sec. 3221(i)(2), Pub. L. 116–136.

■ 41. Amend § 164.520 by:

■ a. Revising paragraphs (a)(1) and removing paragraph (a)(3);

■ b. Redesignating paragraph (a)(2) as (a)(3) and adding a new paragraph (a)(2);

■ c. Revising paragraphs (b)(1) introductory text, (b)(1)(i), b)(1)(ii)(C), (b)(1)(ii)(D), and (b)(1)(iii);

■ d. Revising paragraphs (b)(1)(iv)(C), (b)(1)(iv)(G), (b)(1)(v)(A), (b)(1)(v)(C), (b)(1)(vii), and (b)(2)(iii);

■ e. Removing paragraph (c)(2)(ii), redesignating paragraphs (c)(2)(iii) and (iv) as (c)(2)(ii) and (iii) and revising newly redesignated (c)(2)(ii) introductory text and (iii) and (c)(3)(iii);

■ f. Adding paragraph (d)(4); and

■ g. Revising paragraph (e).

The revisions and additions read as follows:

§ 164.520 Notice of privacy practices for protected health information

(a) * * * (1) *Right to notice.* Except as provided by paragraph (a)(3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Notice requirements for covered entities creating or maintaining records subject to 42 U.S.C. 290dd–2(a).* As provided in 42 CFR 2.22, an individual who is the subject of records protected under 42 CFR part 2 has a right to adequate notice of the uses and disclosures of such records, and of the individual's rights and the covered entity's legal duties with respect to such records.

(3) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(b) * * * (1) *Required elements.* The covered entity, including any covered entity maintaining or receiving records subject to 42 U.S.C. 290dd–2, must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed:

NOTICE OF PRIVACY PRACTICES OF [NAME OF COVERED ENTITY, AFFILIATED COVERED ENTITIES, OR ORGANIZED HEALTH CARE ARRANGEMENT, AS APPLICABLE]

THIS NOTICE DESCRIBES:

- HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED
- YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION
- HOW TO EXERCISE YOUR RIGHT TO GET COPIES OF YOUR RECORDS AT LIMITED COST OR, IN SOME CASES, FREE OF CHARGE
- HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY, OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION, INCLUDING YOUR RIGHT TO INSPECT OR GET COPIES OF YOUR RECORDS UNDER HIPAA

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) * * *

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, such as 42 CFR part 2, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law, such as 42 CFR part 2.

* * * * *

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) or (B) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan;

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose protected

health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes;

(D) Substance use disorder treatment records received from programs subject to 42 CFR part 2, or testimony relaying the content of such records, shall not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in 42 CFR part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed; or

(E) If a covered entity that creates or maintains records subject to 42 CFR part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, a statement that such information may be used or disclosed for such purpose only if the individual grants written consent as provided in 42 CFR 2.31.

(iv) * * *

(C) The right of access to inspect and obtain a copy of protected health information at limited cost or, in some cases, free of charge; and the right to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health record to a third party, as provided by § 164.524;

* * * * *

(G) The right to discuss the notice with a designated contact person identified by the covered entity pursuant to § 164.520(b)(vii);

(v) * * *

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices, and to notify affected individuals following a breach of unsecured protected health information;

* * * * *

(C) A statement that the covered entity reserves the right to change the terms of its notice, provided that such terms are not material or contrary to law, and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

* * * * *

(vii) *Contact.* The notice must contain the name or title and telephone number and email for a designated person who is available to provide further information and answer questions about the covered entity's privacy practices, as required by § 164.530(a)(1)(ii).

* * * * *

(2) * * *

(iii) A covered entity may provide in its notice information about how an individual who seeks to direct protected health information to a third party, when the protected health information is not in an electronic health record or is in a non-electronic format, can instead obtain a copy of protected health information directly under § 164.524 and send the copy to the third party themselves, or request the covered entity to send a copy of protected health information to a third party using a valid authorization under § 164.508.

* * * * *

(c) * * *

(2) * * *

(ii) If the health care provider maintains a physical service delivery site:

* * * * *

(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) * * *

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service.

* * * * *

(d) * * *

(4) The permission in paragraph (c)(1) of this section for covered entities who are part of an organized health care arrangement to issue a joint notice may not be construed to remove any obligations or duties of entities creating or maintaining records subject to 42 U.S.C. 290dd–2, or to remove any rights of patients who are the subjects of such records.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity.

Dated: November 21, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–25784 Filed 11–28–22; 8:45 am]

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